



# In the Interest of Public Health: A Strategic Approach to Defining the FDA's Role in Eliminating Health Disparities

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**IN THE INTEREST OF PUBLIC HEALTH: A STRATEGIC APPROACH TO  
DEFINING THE FDA'S ROLE IN ELIMINATING HEALTH DISPARITIES**

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## **ABSTRACT**

In October of 1985, the Department of Health and Human Services' (DHHS') Secretary's Task Force on Black and Minority Health released a report documenting inequities in the health status of African Americans and other minority groups. Since the report's release, numerous federal agencies have implemented programming to address the issue, and Congress has passed legislation in efforts to eliminate the inequities. The Food and Drug Administration, however, has remained largely silent on the issue. This paper identifies and defines racial and ethnic disparities in health status, discusses the history of government responses to health disparities, and applies the new Office of Minority Health *Strategic Framework* as a guide for defining the role the FDA can and should play in the effort to eliminate racial and ethnic health disparities.

## I. WHAT ARE HEALTH DISPARITIES?

Health disparities have been defined as “those differences in health status among population groups which are avoidable and which are unfair or seen as unfair.”<sup>1</sup> More precise definitions can vary, depending on the disease, and can be measured by differences in incidence, mortality, or survival rates, among other indicators.<sup>2</sup> This paper mainly addresses racial and ethnic disparities in health *status*, as opposed to disparities in health *care*. Health status indicators refer to incidences of mortality (death) or morbidity (illness); whereas health care indicators typically measure differences in treatment approaches. These racial and ethnic differences in health status “often result from the effects of life long, intergenerational social exclusion (e.g., racism and socioeconomic disadvantage).”<sup>3</sup> Despite efforts to reduce or eliminate the inequalities through social policies and changes to the health care system, the differences have persisted<sup>4</sup> and “likely represent a nexus between historic socioeconomic disadvantage, racism and residential segregation.”<sup>5</sup>

In October of 1985, the Department of Health and Human Services’ (DHHS’) Secretary’s Task Force on Black and Minority Health released a report documenting inequities in the health status of African Americans and other minority groups.<sup>6</sup> The Task Force was commissioned the

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<sup>1</sup> Institute for Alternative Futures, The DRA Project, Most Important Disparity Reducing Advances in US Healthcare & Public Health 4 (2006).

<sup>2</sup> *Id.*

<sup>3</sup> Kevin Fiscella, *Eliminating Disparities in Healthcare Through Quality Improvement*, in ELIMINATING HEALTHCARE DISPARITIES IN AMERICA: BEYOND THE IOM REPORT 141, 142 (Richard Allen Williams ed., 2007).

<sup>4</sup> Randall W. Maxey and Richard Allen Williams, *Second-Class Medicine: Implications of Evidence-Based Medicine for Improving Minority Access to the Correct Pharmaceutical Therapy*, in ELIMINATING HEALTHCARE DISPARITIES IN AMERICA: BEYOND THE IOM REPORT 99, 100 (Richard Allen Williams ed., 2007) (“Health inequality represents one of the most persistent, ubiquitous, and troubling phenomena in the United States health system.”).

<sup>5</sup> Fiscella, *supra* note 3, at 143.

<sup>6</sup> Centers for Disease Control and Prevention, Perspectives in Disease Prevention and Health Promotion Report of the Secretary's Task Force on Black and Minority Health, 35(8) Morbidity and Mortality

prior year “in response to the national paradox of steady improvement in overall health, with substantial inequities in the health of U.S. minorities.”<sup>7</sup> The report was the result of a comprehensive review of morbidity and mortality data regarding Black, Hispanic, Asian/Pacific Islander, and Native American populations in relation to whites. It was the first study of its kind to explore the persistent racial inequalities in health outcomes on such a comprehensive scale.<sup>8</sup> The study consisted of a review of mortality data for over forty disease categories to determine areas where minority populations experience “excess deaths” – defined as “the difference between the number of deaths observed in the minority populations and the number that would have been expected if the minority population had the same age- and sex-specific death rates as the nonminority population.”<sup>9</sup> For specific causes of death that were deemed priority areas, the Task Force formed subcommittees which then conducted additional research on the “etiology; associated physiologic, cultural, and societal factors; means for improving treatment; and possible intervention strategies to prevent excess deaths in minority groups.”<sup>10</sup> The subcommittees also considered non-medical determinants of health, including demographic information and health education.<sup>11</sup> Researchers found that eighty percent of the excess mortality of these minority groups could be attributed to six causes of death: Cancer, Cardiovascular Disease and Stroke, Chemical Dependency, Diabetes, Homicides and Unintentional Injuries, and Infant Mortality.<sup>12</sup> In light of these findings, the report outlined

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Weekly Report 109 (1986), <http://www.cdc.gov/mmwr/preview/mmwrhtml/00000688.htm> (last visited May 15, 2008).

<sup>7</sup> *Id.*

<sup>8</sup> See Garth Graham, *Quality of Care and Health Disparities: The Evolving Role of the Government*, in ELIMINATING HEALTHCARE DISPARITIES IN AMERICA: BEYOND THE IOM REPORT 197, 201 (Richard Allen Williams ed., 2007) (Providing general overview of the 1985 Task Force Report).

<sup>9</sup> Centers for Disease Control and Prevention, *supra* note 6.

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> *Id.* The findings of the 1985 Task Force with respect to these six causes are summarized below:

several recommendations and specific actions that DHHS should take to eliminate these disparities in health.<sup>13</sup>

Over twenty years after the release of the Task Force report, health disparities have persisted. According to statistics from the Centers for Disease Control and Prevention, “African Americans are more likely than any other racial and ethnic group to develop cancer, and 30 percent more likely than whites to die from it. Hispanics living in the United States are 50

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Cancer. Cancer accounts for 16% of excess mortality among black males under age 70 years and 10% for black females. Cardiovascular disease and stroke. Cardiovascular diseases account for 24% of excess mortality among black males and 41% among black females. Chemical dependency, measured by deaths due to cirrhosis. Cirrhosis of the liver, which is associated with excessive use of alcohol, accounts for 13% of excess mortality among Native American males and 22% among Native American females under age 70 years. Diabetes. Diabetes accounts for 38% of excess deaths among Mexican-born Hispanic females. Homicides and accidents (unintentional injuries). Homicides account for 60% of excess mortality among Hispanics under 65 years of age. Unintentional injuries account for 44% of excess deaths among male, and 30% among female, Native Americans. Homicides and unintentional injuries account for 19% of excess mortality among black males under age 70 years and 38% for those under age 45 years. For black females, the disparities are somewhat less--6% and 14%, respectively. A substantial proportion of excess deaths due to homicide and unintentional injury may be associated with excessive use of alcohol and other drugs. Infant mortality. Of excess deaths among black females up to age 45 years, death in the first year of life accounts for 35% of that excess. The relative ratio of average age-adjusted, sex-specific mortality in minority populations, compared to that in the nonminority population, by selected cause, suggests the relative importance of specific health problems within each group. *Id.*

<sup>13</sup> *Id.*

The Task Force made eight main recommendations to the Secretary, each of which was followed by several specific suggestions:

1. Implement an outreach campaign, specifically designed for minority populations, to disseminate targeted health information, educational materials, and program strategies.
2. Increase patient education by developing materials and programs responsive to minority needs and by improving provider awareness of minority cultural and language needs.
3. Improve the access, delivery, and financing of health services to minority populations through increased efficiency and acceptability.
4. Develop strategies to improve the availability and accessibility of health professionals to minority communities through communication and coordination with nonfederal entities.
5. Promote and improve communication and coordination among federal agencies in administering existing programs for improving the health status and availability of health professionals to minorities.
6. Provide technical assistance and encourage efforts by local and community agencies to meet minority-health needs.
7. Improve the quality, availability, and use of health data pertaining to minority populations.
8. Adopt and support research to investigate factors affecting minority health, including risk-factor identification, education interventions, and prevention and treatment services. *Id.*

percent more likely than whites to suffer from diabetes, and the incidence of diabetes among Native Americans is more than twice that for whites.”<sup>14</sup>

The persistent trend of racial and ethnic minority groups experiencing higher morbidity and mortality rates is a public health concern because much of the disparity is observed for preventable diseases and conditions.<sup>15</sup> Research has shown that socioeconomic conditions in minority communities such as “less access to healthy foods; fewer opportunities for physical activity; and constant advertising of alcohol, cigarettes, and junk food” play a role in increasing the risk for these diseases.<sup>16</sup> Many of the corresponding risk factors can be mitigated through increased government regulation with attention to public health concerns; however, such policy efforts cannot ignore the impact that America’s history of segregation and prejudice has had on both the health care sector and on other social factors that can impact health. The health status and health care inequities observed by race are often rationalized as variations by socioeconomic status or health insurance; however there is evidence that race “in many instances has an independent effect on health; that is, the effects of race cannot be fully accounted for by the other indicators of rank.”<sup>17</sup> America bears the burden of its long history of the enslavement, internment, and segregation of various minority groups, and the impact of this relationship on the health of certain populations cannot be ignored. More than just reflecting differences in health status, health disparities represent a social injustice in American society, which “leads to a wide range of adverse health consequences, as reflected by disparities in health status and access to

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<sup>14</sup> Edward M. Kennedy, *The Role of the Federal Government In Eliminating Health Disparities*, 24 Health Affairs 452, 452.

<sup>15</sup> *Id.* at 456.

<sup>16</sup> *Id.*

<sup>17</sup> David Mechanic, *Disadvantage, Inequality, And Social Policy*, 21 Health Affairs 48, 48 (2002).

health services within or between populations.”<sup>18</sup> As with any social injustice, it is the responsibility of the relevant government authorities to legislate, regulate, and take all necessary measures to right the wrongs.<sup>19</sup>

Since the causes of disparities in health status lie well beyond simply differences in health *care*, adequately addressing health disparities requires adopting a holistic and comprehensive view of health. The World Health Organization (WHO) has defined health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”<sup>20</sup> The Organization has developed a Commission on Social Determinants of Health that “examines a similarly broad range of social factors, including water, sanitation, and food production.”<sup>21</sup> The persistence of inequalities in health status over the past few decades of measurement has shown that answering the question of why some people are healthier than others requires a similarly broad examination of the societal contributors to health and the ways in which the government can intervene to protect disadvantaged populations in the interest of public health.

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<sup>18</sup> Barry S. Levy and Victor W. Sidel, *The Nature of Social Injustice and Its Impact on Public Health*, in SOCIAL INJUSTICE AND PUBLIC HEALTH 5, 7 (Barry S. Levy and Victor W. Sidel eds., 2006).

<sup>19</sup> *Id.* at 13.

<sup>20</sup> Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948., <http://www.who.int/about/definition/en/print.html> (last visited May 16, 2008).

<sup>21</sup> Institute for Alternative Futures, The DRA Project, *supra* note 1 at 12.



## II. THE GOVERNMENT RESPONSE

### AGENCY ACTION

In the immediate wake of the 1985 Task Force report, the U.S. Department of Health and Human Services (DHHS) created an Office of Minority Health (OMH) to take the lead in research and programmatic efforts to eliminate disparities. OMH is charged with “improv[ing] and protect[ing] the health of racial and ethnic minority populations through the development of health policies and programs that will eliminate health disparities.”<sup>22</sup> In the early 1990s, the Clinton administration implemented several programs to address health disparities, including the Healthy People 2010 initiative, Health Disparity Collaboratives, Racial and Ethnic Approaches to Community Health (REACH), and Excellence Centers to Eliminate Ethnic/Racial Disparities (EXCEED).<sup>23</sup> Several agencies within DHHS also took the initiative to implement targeted programs of their own. In 1998, the Health Resources and Services Administration (HRSA) identified six priority areas for reducing health disparities: Infant Mortality, Cancer Screening and Management, Cardiovascular Disease, Diabetes, HIV/AIDS, and Immunizations.<sup>24</sup>

The release of another report, this time issued by the Institute of Medicine (IOM), created a flurry of government activity over health disparities again in 2002. The report, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, showed that these inequities had persisted since 1985, and it outlined the areas in which African Americans and other minority groups were receiving lower quality health care or were experiencing poorer

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<sup>22</sup> The Office of Minority Health, About OMH, <http://www.omhrc.gov/templates/browse.aspx?lvl=1&lvlID=7> (last visited May 16, 2008).

<sup>23</sup> Kennedy, *supra* note 14 at 453.

<sup>24</sup> Institute for Alternative Futures, The DRA Project, *supra* note 1 at 7-8.

health outcomes.<sup>25</sup> After the report's release, the term "health disparity" entered the common vernacular within the government and became an urgent policy matter. In addition to the formation of the Office of Minority Health within the Department of Health and Human Services, nearly every state established their own Office of Minority Health.<sup>26</sup> Furthermore, several of the major agencies within DHHS have either created an office of minority health to address relevant concerns or have dedicated a section on their websites to minority issues.<sup>27</sup> However, developing a federal agency-level response to combat health disparities presents a challenge because "[t]he federal government and the public in general have never defined an overarching strategy for investing in the health of the nation."<sup>28</sup>

While congressional awareness of and attention to the problem of health disparities is growing, a persistent focus on solely medical interventions as a solution<sup>29</sup> overlooks the many social factors at play. Many of the public policies advocated through government efforts have focused on direct access to medical services as the primary approach to reducing disparities, and some of the literature on health disparities argues that "[t]he most important immediate action in response to social injustice against racial and ethnic minorities that leads to disparate health

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25 Smedley, Brian D., Adrienne Y. Stith, and Alan R. Nelson, Eds., *Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care, Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* (National Academies Press, 2003), <http://www.iom.edu/?id=16740>.

26 See Office of Minority Health Resource Center, State Offices of Minority and Multicultural Health Liaison Map, <http://www.omhrc.gov/images/stateliasions.htm> (last visited May 16, 2008).

27 See generally, Administration on Aging, <http://www.aoa.gov/prof/adddiv/adddiv.asp>; AHRQ, <http://www.ahrq.gov/research/minorix.htm>; Centers for Disease Control and Prevention, Office of Minority Health and Health Disparities, <http://www.cdc.gov/omhd/Default.htm>; Health Resources and Services Administration, <http://www.ask.hrsa.gov/Minority.cfm>; National Institutes of Health, National Center on Minority Health and Health Disparities, <http://www.ncmhd.nih.gov/>.

28 Nicole Lurie, *What The Federal Government Can Do About The Nonmedical Determinants of Health*, 21 *Health Affairs* 94, 102 (2002).

29 Kennedy, *supra* note 14 at 453. Senator Kennedy asserts, "Most members of Congress would agree that the progress is far from adequate. Fortunately, more and more members on both sides of the aisle are increasingly concerned by the severity of the minority health crisis and understand the need to address it more effectively, through a federal action plan that increases minorities' access to health care and improves the quality of care they receive."

outcomes is the equitable provision of health care.”<sup>30</sup> However, this approach ignores the importance of social and environmental factors.

Not all aspects of the government response have even accepted the existence of disparities outright, however. A 2003 Institute of Medicine report was censored before its release to “strike the term *disparity* from a congressionally mandated annual report on – ‘healthcare disparities.’”<sup>31</sup> HHS leaders also ordered the researchers to “delete their conclusion that racial disparities are ‘pervasive in our healthcare system’ and to remove findings of disparity in care for cancer, cardiac disease, AIDS, asthma, and other illnesses.”<sup>32</sup> While the full report was later released after news of the censorship leaked, the controversy highlighted the fact that efforts to develop strategies to address the problem may face the additional obstacle of convincing officials with the power for change that a race-specific problem worth addressing exists at all.

## A LEGISLATIVE HISTORY

In 2007, the Minority Health and Health Disparity Elimination Act was introduced into the Senate.<sup>33</sup> If enacted, the bill “would authorize nearly \$500 million to improve health care for racial and ethnic minority and other health disparity populations.”<sup>34</sup> Additionally, the proposed

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<sup>30</sup> Carol Easley Allen and Cheryl E. Easley, *Racial and Ethnic Minorities, in Social Injustice and Public Health* 46, 63 (Barry S. Levy and Victor W. Sidel eds., 2006).

<sup>31</sup> M. Gregg Bloche, *Healthcare and the Politics of Race, in ELIMINATING HEALTHCARE DISPARITIES IN AMERICA: BEYOND THE IOM REPORT* 67, 68 (Richard Allen Williams ed., 2007) (internal citations omitted).

<sup>32</sup> *Id.*

<sup>33</sup> Minority Health Improvement and Health Disparity Elimination Act, H.R.3333/S.1576, 110<sup>th</sup> Cong. (1st Sess. 2007).

<sup>34</sup> Barack Obama – U.S. Senator for Illinois, Obama Introduces Bill to Eliminate Health Care Disparities, June 7, 2007, [http://obama.senate.gov/press/070607-obama\\_introduce\\_13/](http://obama.senate.gov/press/070607-obama_introduce_13/) (last visited May 16, 2008); see Minority Health Improvement and Health Disparity Elimination Act, H.R.3333/S.1576, 110<sup>th</sup> Cong. (1st Sess. 2007).

legislation “reauthorizes and strengthens the Office of Minority Health, mandates uniform data collection standards for federal health programs and creates an advisory committee at the FDA to address genomic issues related to racial and ethnic minorities.”<sup>35</sup> This bill is just the latest in the effort to address the persistence in health disparities through legislation.

In 2000, Congress passed the Minority Health and Health Disparities Research and Education Act. The Act mandated that several agencies take direct action to research and collect data on health disparities and created the National Center for Minority Health and Health Disparities at the National Institutes of Health (NIH).<sup>36</sup> Additionally, the new law required the Agency for Healthcare Research and Quality (AHRQ) to research minority health and health disparities and called for the National Academy of Sciences to review the minority data collection practices of the Department of Health and Human Services (DHHS).<sup>37</sup> In 2004, the National Academy of Sciences released the results of its review in a report titled *Eliminating Health Disparities: Data and Measurement Needs*, outlining current federal data collection practices.<sup>38</sup> AHRQ fulfilled its mandate by releasing “annual reports on health care quality and health care disparities, which has allowed better monitoring and evaluation of trends in the care of minority and other underserved populations.”<sup>39</sup> Congress also addressed health disparities through a provision in the 2000 appropriations bill requiring the Institute of Medicine to research the potential causes of racial and ethnic health disparities. The resulting report, *Unequal Treatment* (referenced above) “is considered the premier study on racial and ethnic disparities and provides actionable recommendations for the medical, public health, and research

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<sup>35</sup> *Id.*

<sup>36</sup> Kennedy, *supra* note 14 at 453.

<sup>37</sup> *Id.*

<sup>38</sup> Dora Hughes, Health Affairs Blog, Minority Health Legislation In The 110<sup>th</sup> Congress (March 14, 2008), <http://healthaffairs.org/blog/2008/03/14/minority-health-legislation-in-the-110th-Congress/>.

<sup>39</sup> *Id.*

communities.”<sup>40</sup> Since 2000, however, several health disparities bills have been introduced but have failed to pass both houses of Congress.<sup>41</sup> Currently, “[t]he prospects for a minority health and health disparities bill being signed into law in 2008 are uncertain. The opposition by some House Democrats as well as some Senate and House Republicans, the inevitable slowdown of congressional activity during election years, and the general difficulty of passing any bill are significant challenges to moving the bill.”<sup>42</sup> These political realities and other potential barriers will be discussed later in addressing the political feasibility of the FDA taking a more prominent role in the fight against health disparities.

## WHERE WE STAND NOW

The recently-released 2007 AHRQ report on healthcare disparities shows little improvement since the initial findings were released, and in some instances the disparities have increased.<sup>43</sup> This regression has been observed by other organizations and agencies attempting to quantify progress as well<sup>44</sup> and indicates that it is time for government agencies to view the

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<sup>40</sup> *Id.*

<sup>41</sup> *Id.* (“In 2003 . . . Democrats in the Senate and the House introduced a democratic caucus minority health bill entitled the Healthcare Equality and Accountability Act (S 1833) . . . Sen. Bill Frist (R-TN) introduced Closing the Health Care Gap (S 2091) in early 2004, which, although more modest in scope, addressed many of the same concerns as the democratic caucus bill. Neither bill passed the Congress, and current efforts have focused on negotiation of bipartisan legislation.”)

<sup>42</sup> *Id.*

<sup>43</sup> Agency for Healthcare Research and Quality, National Healthcare Disparities Report iv (2007), <http://www.ahrq.gov/qual/nhdr07/Glance.htm> (last visited May 16, 2008).

Overall, disparities in quality and access for minority groups and poor populations have not been reduced since the first NHDR. Based on 2000 and 2001 data compared with this year's 2004 and 2005 data (depending on the data source), the number of measures on which disparities have gotten significantly worse or have remained unchanged since the first NHDR is higher than the number of measures on which they have gotten significantly better for Blacks, Hispanics, American Indians and Alaska Natives, Asians, and poor populations. *Id.*

<sup>44</sup> The Office of Minority Health, A Strategic Framework for Improving Racial/Ethnic Minority Health and Eliminating Racial/Ethnic Health Disparities (20008), <http://www.omhrc.gov/npa/templates/content.aspx?ID=78&lvl=1&lvlID=13> (last visited May 16, 2008) (“In many cases, the health gaps identified in the 1985 *Task Force Report* have grown.”).

problem holistically and to implement creative policies that will improve the health of minority communities. In April of 2008, the Office of Minority Health announced the release of a *Strategic Framework for Improving Racial and Ethnic Minority Health and Eliminating Racial and Ethnic Health Disparities*.<sup>45</sup> The report mentioned that “[t]he ultimate goal, for all stakeholders, is that individual and collective efforts on behalf of racial/ethnic minority health will be more evidence-based and will use available resources effectively and efficiently.”<sup>46</sup>

## A STRATEGIC FRAMEWORK

In April of 2008, DHHS’ Office of Minority Health released a Strategic Framework for Improving Racial/Ethnic Minority Health and Eliminating Racial/Ethnic Health Disparities.<sup>47</sup> The document “reflects current knowledge and understanding of the nature and extent of health disparities, their causes or contributing factors, effective solutions and desired outcomes and impacts.”<sup>48</sup> The framework emphasizes what it calls a “systems approach” – an approach where “all parties engaged . . . are, themselves, part of a ‘system’ or ‘nested’ systems. As such, each party considers the causal or contributing factors and problems it is most likely to be able to impact with its particular strengths and talents.”<sup>49</sup> The components of the five-part strategy include:

(1) examination of the *long-term problems* that OMH and others are trying to address, (2) review of the *major factors known to contribute to or cause the long-term problems*, (3) identification of promising, best and/or evidence-based *strategies and practices* known to impact the causal or contributing factors, (4) presentation of measurable *outcomes and impacts* that might be expected from the

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<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

strategies and practices and (5) assessment of the extent to which *long-term objectives and goals* have been achieved.<sup>50</sup>

The framework can serve as a strategic planning guide for agencies to determine approaches and initiatives that may be successful in addressing disparities.<sup>51</sup> Specifically, application of this framework can help to define the role the FDA can and should play in the effort to eliminate racial and ethnic health disparities.

### **III. THE ABSENT PLAYER – THE FDA**

Despite the broad range of federal initiatives outlined above, the Food and Drug Administration (FDA) has largely been absent from the department-wide initiatives to reduce and/or eliminate health disparities.<sup>52</sup> This absence is troubling, considering the breadth of the FDA’s regulatory authority and its control over several markets that directly affect the health of consumers: “Products accounting for no less than 25 cents of every dollar spent by American consumers are under the jurisdiction of the FDA, approximately \$1 trillion annually, including all foodstuffs excepting meat and poultry and all human and animal drugs and therapeutic devices.”<sup>53</sup> The breadth of this regulatory authority shows that the FDA is optimally placed to have a true impact in terms of implementing healthier changes in the way food products are made and distributed.<sup>54</sup> Yet, even legislators tend to overlook the broad reach of the FDA in drafting legislation to focus on health disparities. The Minority Health and Health Disparity

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<sup>50</sup> *Id.*

<sup>51</sup> “The framework is intended to “help enhance the understanding of policymakers, policy analysts, researchers, practitioners and others about the key strategic components that must be addressed in developing policies or programs that affect racial and ethnic minority populations.” *Id.*

<sup>52</sup> *See* Lurie, *supra* note 28. (listing contributions of various government departments to leading health indicators. The FDA is not listed.).

<sup>53</sup> Ronald Hamowy, *Government and Public Health in America* 103 (2007).

<sup>54</sup> *Id.* ([The FDA] “ultimately has the power of life and death over hundreds of thousands of people suffering from fatal illnesses. We must all, at one point or another, rely on the FDA’s permission to obtain and ingest what might prove a life-saving medication prescribed by our physician without which we might well die.”]

Elimination Act introduced in 2007 proposes to implement “an FDA advisory committee on pharmacogenomics and emerging issues,”<sup>55</sup> but fails to suggest any other creative solutions involving the FDA that could be reached through legislation relating to food safety, quality or nutrition. With the FDA’s enormous authority should come the equally sizeable responsibility to act to protect and advance the public’s health with regard to health disparities. The new Office of Minority Health Framework can provide guidance in assessing the FDA’s current and future role in this effort.

### **APPLYING THE FRAMEWORK**

- 1) *Long-Term Problems*
- 2) *Contributing Factors*
- 3) *Support Effective Strategies and Practices*
- 4) *Measure Intermediate Outcomes and Long-Term Impacts*
- 5) *Achieve Long-Term Objectives and Goals*

Step one involves identifying the long-term problems. This category also entails identifying the system-level “conceptual, organizational, structural and process-related variables that influence the ability to adequately and effectively address complex problems – and that can exacerbate these problems, or constitute problems in their own right.”<sup>56</sup> Regarding disparities in health status, the problem is clear: racial and ethnic minority groups experience poorer health than other population groups, and these disparities have persisted despite numerous public health interventions. This first step also calls for an analysis of the “extent to which the systems (and the strategies/practices) are well-coordinated and strategically directed, and the extent to which

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<sup>55</sup> Barack Obama – U.S. Senator for Illinois, *supra* note 34.

<sup>56</sup> Office of Minority Health, *supra* note 44.



existing stakeholder groups are willing to work together as parts of an interconnected system.”<sup>57</sup>

While the FDA does not currently play a major role in the effort to eliminate health disparities, other agencies have developed initiatives and have coordinated efforts in some cases.

Step two divides the possible contributing factors in to three categories: individual factors, environmental or community factors, and systems factors.<sup>58</sup> Individual factors refer to the “knowledge, attitudes, skills, behaviors and biological or genetic risks” that impact health. Examples of environmental or community factors include “the physical environment (both natural and built), social and cultural characteristics of a community, and other economic, political and organizational/institutional conditions that are not generally within the control of specific individuals but provide the context of their lives.”<sup>59</sup> Finally, systems factors “include the kinds of systems that a community, state, region or nation might have (or not have), and approaches used (or not used), for identifying the problems or needs – health-related or otherwise – in their respective jurisdictions and for directing resources to address the problems or needs.”<sup>60</sup> As a federal agency, the FDA’s actions constitute systems-level factors that affect the problem. However, the FDA has the ability, through regulation, to impact both individual and community level factors as well. For example, the agency requires clinical studies that contribute to increasing the knowledge base and regulates the safety of the food supply in the community.

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<sup>57</sup> *Id*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.* (“These factors may be either protective of, or pose risks to, health. Such factors include, but are not necessarily limited to: natural and physical hazards or **biochemical risks**, crime and violence, cultural values and norms that influence **individual behavior** and can protect or hinder the health and well-being of residents within communities, bias and discrimination, housing conditions and residential segregation, access to and quality of health care as well as schools, parks and recreational sites, **nutritious food sources**, transportation and other goods and services, communication networks and infrastructure, family and social networks or other supports for diverse segments of the community, low-income and poverty, unemployment, and the lack of health insurance.”) (emphasis added).

<sup>60</sup> *Id.*

Step three involves incorporating effective strategies and practices to address the factors at every level outlined in step two. Successful individual-level approaches “tend to reflect integrated approaches that address a combination of individual-level factors as well as their interactions with environmental factors that inhibit or support desired behaviors.”<sup>61</sup> Community-level strategies include the “promotion of a healthy physical environment through the development of policies that promote public health and safety.”<sup>62</sup> The systems level strategies are especially important as they relate to the FDA’s role as an agency. The framework recommends “[e]stablish[ing], increas[ing] and strengthen[ing] system components and resources, such as infrastructure, staffing and funding to ensure specific attention to racial/ethnic minority health and health disparities.”<sup>63</sup> Because of the tension between the government’s efforts to address public health concerns and the public’s desire to be free from government intervention, most public health initiatives to date have targeted personal responsibility and have touted measures that individuals can take on their own to improve their health. However, initiatives targeting individuals may actually increase health disparities because disadvantaged groups may be in less of a position to make changes, while the status of advantaged groups will improve.

“To the extent that health initiatives are not tied to individual action, all social groups are more likely to benefit in comparable ways. Thus, fluoridation of water supply, fortified foods, or environmental controls that reduce toxic pollution, such as the elimination of lead from gasoline and paints, are less likely to result in disparities than initiatives encouraging voluntary efforts such as educational campaigns to promote careful tooth brushing, preventive fluoride treatment, increased exercise, or improved nutrition.”<sup>64</sup>

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<sup>61</sup> *Id.* (“In addition, health messages are more readily accepted if they do not conflict with existing cultural beliefs and practices, and take into account unique historical and cultural experiences of target audiences, including racial and ethnic minorities.”)

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> Mechanic, *supra* note 17.

Thus, the FDA's strategic approaches should consider incorporating community-level interventions that will provide benefits regardless of the capabilities of any one individual.

Step four involves measuring intermediate outcomes and long-term impacts. Once again, this step is subdivided along the three categories of contributing factors to health disparities.<sup>65</sup>

While the report lists a range of expected outcomes, relevant outcomes include:

*Decreased exposure to risks in the physical environment; Increased community assets that are protective of the health and well-being of its residents (e.g., health centers in underserved communities, neighborhood restaurants and grocers with healthy food options, faith-based organizations, gathering place); Increased engagement in/adoption of healthy lifestyle and appropriate health-seeking behaviors, reduced engagement in/adoption of risky behaviors; Increased inputs, assets and other resources allocated for racial/ethnic minority health and health disparities – in general and for specific priorities; and Increased dedicated assets and other resources for minority health/health disparities (including, but not limited to, state offices of minority health) and related priorities (as reflected in administrative, legislative, budgetary and other mandates).*<sup>66</sup>

As the FDA mainly serves a protective role in ensuring the safety and efficacy of the foods and drugs that we ingest, its overall objective should be to decrease exposure to the risks that contribute to poor health outcomes. In achieving this outcome, the FDA should work within its regulatory authority to ensure the availability of healthy food options and should dedicate resources to explore the role foods and drugs have played in creating and maintaining racial and ethnic health disparities.

Finally, step five emphasizes establishing and measuring progress in achieving the long-term goals. This final step is critical and involves the recognition that health disparities are a problem that was created over time and that will take time to eliminate. Unfortunately, as noted by Nicole Lurie in discussing the role of the federal government in improving social determinants of health, “Our nation’s investment portfolio with regard to health is weighted far toward short-term

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<sup>65</sup> *Id.*

<sup>66</sup> *Id.* (emphasis added).

returns.”<sup>67</sup> As a public health agency, the FDA should commit itself to help minimizing the inequitable death and disability caused by preventable health hazards that can be found in food as well.<sup>68</sup>

#### **IV. HISTORICAL APPROACHES AND MISSED OPPORTUNITIES**

Despite its failure to launch a comprehensive approach to eliminating health disparities, the FDA has not been *entirely* silent in the debate over the last twenty years. Several regulatory decisions and high-profile litigation cases drew attention to the role that the foods we eat and the medications we take plays in health status, especially for minorities and socioeconomically disadvantaged populations. However, some of these controversies also exposed the opportunities that the FDA has missed to both become a leader in the fight against health disparities and to develop viable strategies to eliminate the harms.

#### **THE BIDIL CONTROVERSY**

The FDA made a decision in 2005 that was heralded by some as a medical breakthrough and a welcome focus on disparities, and condemned by others as a step backward toward racist characterizations of genetic inferiority. The agency approved a heart medication to be marketed exclusively to African American patients. The drug, called BiDil, is not entirely original, but combines two generic medications “long recognized as benefiting patients with heart failure, irrespective of race or ethnicity.”<sup>69</sup> Medco, a pharmaceutical company based in North Carolina,

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<sup>67</sup> Lurie, *supra* note 28.

<sup>68</sup> “Public health is ultimately and essentially an ethical enterprise committed to the notion that all people are entitled to protection against the hazards of this world and to the minimization of death and disability in society.” Levy and Sidel, *supra* note 18 at 6.

<sup>69</sup> Pamela Sankar and Jonathan Kahan, BiDil: Race Medicine or Race Marketing? Health Affairs (Web Exclusive) 455 (2005).

sought to obtain exclusive patent rights to the generic combination by submitting a new drug application (NDA).<sup>70</sup> The FDA originally rejected the NDA for BiDil because the 20-year old statistical data submitted in support of the application did not meet certain FDA statistical guidelines.<sup>71</sup> After the application was denied, researchers re-analyzed the data by race and found that the African American patients in the study were significantly more responsive to the therapy.<sup>72</sup> The researchers then obtained a new methods patent that specified the drug's use "in an African American patient"<sup>73</sup> and licensed the drug to the biotechnology company NitroMed.<sup>74</sup> In 2001, NitroMed announced that it had received a letter from the FDA "commenting on the ultimate approvability of BiDil as a race-specific drug, pending the successful completion of a confirmatory trial in African American subjects."<sup>75</sup> The company then conducted the African American Heart Failure Trial (A-HeFT) to test the drug in heart failure patients who self-identified as African American.<sup>76</sup> The results of the trial showed a significant increase in survival rates for those in the treatment group – so significant, in fact, that the trial was discontinued because continuing to deny treatment to the placebo group would have been considered unethical.<sup>77</sup> In the approval decision, the FDA "depart[ed] from its long history of approving drugs for general clinical indications without regard to demographic classification, . . .

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<sup>70</sup> *Id.* at 456-457. (Jay Cohn, the lead cardiologist who conducted the original V-HeFT studies had obtained a "methods" patent for combining hydralazine and isosorbide dinitrate (H/I) to treat heart failure. He licensed this patent to Medco.).

<sup>71</sup> *Id.*

<sup>72</sup> *Id.* at 457.

<sup>73</sup> *Id.*

<sup>74</sup> *Id.* at 457.

<sup>75</sup> *Id.*

<sup>76</sup> Institute for Alternative Futures, *supra* note 1.

<sup>77</sup> *Id.*; see Sankar and Kahn, *supra* note 69 at 458.

[and] cited the need to address racial disparities in health as an important contributor to their decision.”<sup>78</sup>

To the extent that personal bias and prejudice may influence the behavior of physicians, initiatives that emphasize biological differences based on race may further disadvantage efforts to encourage physicians to regard patients equally. The FDA’s decision has been called “a setback in the scientific and policy discourse on medical therapeutics and race [that] . . . specifically hinders the efforts aimed at eliminating health and health care disparities.”<sup>79</sup> One article summarized the concerning implications of BiDil’s approval as follows:

(1) Drug approval for specific groups implies a differential drug response that has not been rigorously tested; (2) In approving a drug for a specific racial group, the FDA creates incentives for pursuing trials in less diverse patient populations; (3) In creating incentives for studies in less diverse patient populations, the FDA decision may lead to a diversion of resources away from studies of better therapeutics to those that support niche marketing; (4) By endorsing race as a treatment indication, the FDA unscientifically endorsed a biological model of race; (5) The use of the health disparities argument to justify approval suggests a “solution” (race-targeted pharmacology) for a “problem” (racial disparities in health) and elevates biological difference in medication response to an important cause of health disparities without evidence; (6) The use of health disparities to justify the “creation” of an expensive medication is perverse.<sup>80</sup>

## PROFIT MOTIVES

Opponents of FDA’s actions argue that “[w]ithout playing the race card, NitroMed might never have raised the money needed to conduct A-HeFT.”<sup>81</sup> However, considering all sides of the debate, the statement is not necessarily a negative fact – had NitroMed not “played the race

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<sup>78</sup> Kirsten Bibbins-Domingo and Alicia Fernandez, *BiDil for Heart Failure in Black Patients: Implications of the U.S. Food and Drug Administration Approval*, 146 *Ann. Intern. Med.* 52, 52 (2007). While it is not clear why the FDA chose to change its position from 1996, it has been suggested that it was influenced by “the growing acceptance – among some, perhaps, a desire – that the response recognize rather than deny racial differences, conceived of as both genetic or biological and social.” Sankahar and Kahn, *supra* note 69 at 459.

<sup>79</sup> Bibbins-Domingo and Fernandez, *supra* note 78 at 52.

<sup>80</sup> *Id.* at 53-55.

<sup>81</sup> Sankar and Kahn, *supra* note 69 at 461.

card,” a drug that that has proven extremely efficacious in saving the lives of African American patients (and unknown numbers of other patients with heart failure), may have never been brought to market. The reality of the American market is that medical interventions are rarely, if ever, pursued in the absence of significant financial incentive. A NitroMed executive even acknowledged this financial incentive, arguing that “developing drugs for underserved populations . . . makes ‘good business sense,’ as these populations have been largely untapped by the pharmaceutical industry.”<sup>82</sup> However, NitroMed’s hiring of an advertising agency best known for its beer and car marketing to handle the marketing of the drug to African Americans is troubling and possibly shows how easily the promise of pharmacogenomics can devolve into racial stereotyping.<sup>83</sup>

Yet another concern is that this focus on genetics-based medicine could potentially lead to more health disparity in terms of treatments. While the new frontier of pharmacogenomics has been touted for the potential to revolutionize medicine through personalized drugs, “little consideration has occurred regarding how pharmacogenomic medicine may affect the principle of distributive justice, and, in particular, who will benefit from newly developed tailored drugs.”<sup>84</sup> Minority groups could be at a disadvantage since engineering drugs for smaller populations would be viewed as less lucrative.<sup>85</sup>

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<sup>82</sup> Sandra Soo-Jin Lee, *Racializing Drug Design: Implications of Pharmacogenomics for Health Disparities*, 95(12) *Am. J. Pub. Health* 2133, 2137 (2005).

<sup>83</sup> Sankar and Kahn, *supra* note 69 at 458. “Anticipating FDA approval, NitroMed hired an advertising agency, Vigilante, known for its work selling beer and cars, to handle the effort.”

<sup>84</sup> Sandra Soo-Jin Lee, *Racializing Drug Design: Implications of Pharmacogenomics for Health Disparities*, 95(12) *Am. J. Pub. Health* 2133, 2137 (2005) (“Although it has been predicted that pharmacogenomics will usher in an era of personalized medicine, population – rather than individual – differences continue to be the focus of much of current research.”) *Id.* at 2133.

<sup>85</sup> *Id.*

## PHARMACOGENOMICS - PROBLEMS AND PROMISES

Amidst the controversy, however, several prominent African American organizations have supported the development of BiDil. The Association of Black Cardiologists (ABC) publicly expressed its support for the A-HeFT trial.<sup>86</sup> However, these groups reject the assertion that BiDil is a “race drug.”<sup>87</sup> Others have condemned the FDA for allowing NitroMed to take advantage of race as a marketing tool to gain increased profit on a drug that could benefit a wider audience,<sup>88</sup> and argue that the agency’s action “threatens to set in motion a trend in the pharmaceutical industry for turning other widely used and cost-effective generics into patented, expensive drugs in the name of alleviating health disparities.”<sup>89</sup> The makers of BiDil initially sought approval of the drug across all populations and only sought the race-specific patent when approval seemed otherwise unlikely – a move that suggests the company was only interested in the benefits it could bring to African Americans if there was a profit potential.<sup>90</sup> The new patent gives NitroMed exclusive marketing rights to market BiDil as a “method” to treat African American patients for heart failure until the year 2020.<sup>91</sup>

According to Sandra Soo-Jin Lee of the Stanford Center for Biomedical Ethics, “[t]he use of race as a proxy for genetic relatedness has been widely criticized. The conflation of race

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<sup>86</sup> Sankar and Kahn, *supra* note 69 at 459.

<sup>87</sup> Medical News Today, *Major Groups Call For FDA Approval of BiDil*, June 15, 2005, <http://www.medicalnewstoday.com/articles/2601.php> (last visited May 16, 2008) (“BiDil has stirred controversy in recent months because some have attempted to categorize it as a race drug. While acknowledging the value of the A-HeFT trial, the groups roundly rejected the designation of BiDil as a ‘race-specific’ drug and pointed instead to [the] possibility that the drug may be beneficial in a broader range of heart failure patients.”) *Id.*

<sup>88</sup> Sankar and Kahn, *supra* note 69 at 455 (“BiDil’s success, however, is one not of personalized medicine but of exploiting race to gain commercial and regulatory advantage in the pharmaceutical marketplace.”).

<sup>89</sup> *Id.* (“By testing BiDil in doses that are not available for its generic components (hydralazine and isosorbide dinitrate), NitroMed has discouraged doctors from easily devising ways for patients to get the same benefits from the long available, and much less expensive, generics.”) *Id.* at 458.

<sup>90</sup> *Id.* at 457. (“The goal of A-HeFT was not to prove that H/I was effective; it was to prove BiDil’s efficacy in such a way that patent law could protect it and an NDA could succeed.”) *Id.* at 460.

<sup>91</sup> *Id.* at 461.



with genetics opens the door to prejudice, racial stereotyping, and overly simplistic conceptualizations of pharmacogenomic interactions, which could ultimately lead to poor health care.”<sup>92</sup> Additionally, there is the concern that this approval paves the way for companies to avoid the costs of gene-specific pharmacogenomic testing by relying on self-identified race instead “as a proxy for genetic variation.”<sup>93</sup>

“The problem with BiDil is not only that it biologizes race but also that it uses race as biology to create the impression that the best way to address health disparities is through commercial drug development. By exploiting race in the service of product promotion, it distorts public understanding of health disparities and of efforts to address them.”<sup>94</sup>

Despite the concerns, there are many promising aspects of pharmacogenomics that have the potential to revolutionize the way medicine is administered. Researchers hope to be able to tailor medications more closely to an individual’s genome to reduce the risk of adverse drug reactions.<sup>95</sup> In addition, the ability to identify and target individuals with genotypes likely to respond to a particular medication could ultimately decrease the cost of clinical trials, since fewer individuals would need to be recruited to observe the drug’s efficacy. However, while this would likely result in drugs receiving approval quicker and at a lower cost, they would be approved for these specific populations alone.<sup>96</sup> This limitation could be of particular concern, since “compelling evidence does exist to support the more reasonable claim that racial or

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<sup>92</sup> Soo-Jin Lee, *supra* note 84 at 2133.

<sup>93</sup> *Id.* at 2136.

<sup>94</sup> Sankar and Kahn, *supra* note 69 at 462.

<sup>95</sup> Soo-Jin Lee, *supra* note 84.

<sup>96</sup> *Id.* (“In developing new drugs, pharmacogenomic testing could be used in clinical trials to identify potential study participants with genotypes associated with an intended drug response. Costs of recruiting participants for phase II clinical trials – in which drugs are examined for efficacy, dosage, and side effects – and phase III clinical trials – in which drugs are further tested against current standards of care and for rare side effects – could decrease by ‘enriching’ the study population with people having the candidate genotypes. As a result, fewer participants would be needed to achieve the anticipated effect, and the time spent on these stages of drug development would decrease. The drug would then be labeled for use only by people with the genotypes in question.”) *Id.* at 2134.

ethnocultural differences in pharmacodynamics may warrant the use of safeguards to protect minority access to needed medications.”<sup>97</sup> While pharmacogenomics brings the promise of personalized medicine, the FDA should consider implementing safeguards to ensure that minority populations will retain access to safe and effective medications even if their genotypes are not deemed profitable.

The FDA should also implement better data collection and analysis protocols for the reporting of adverse events by race and ethnicity.<sup>98</sup> While differences in efficacy have been seen to vary by race/ethnicity, a systematic data collection system is needed.<sup>99</sup> “[S]cientists have copiously reported racial and ethnic *healthcare* disparities across an impressive array of disease, whereas simultaneously *underreporting* on therapeutic safety and efficacy for minority populations.”<sup>100</sup> Finally, the FDA should not ignore the potential for discrimination to cloud the promise of pharmacogenomics. While some researchers argue that advances in genome mapping and genetic technologies will “render race, as defined by distinctive genetic signatures, obsolete . . . [u]nderlying this prediction of a race-free genomic era is the assumption that research on human genetic variation will proceed untainted by dominant social ideas and values regarding what constitutes human difference.”<sup>101</sup>

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<sup>97</sup> Maxey and Williams, *supra* note 4 at 105.

<sup>98</sup> *Id.* at 105 (“[F]or racial and ethnic minority populations, data on the true efficacy and safety of innumerable therapeutic interventions is substantially nonexistent.”).

<sup>99</sup> *Id.* (“Cardiovascular, psychotropic, and central nervous system drugs are among the many classes of drugs known to have such differential effects between racial and ethnic groups. Examples include (1) the increased sensitivity of Asians to antidepressants; (2) the marked effectiveness of certain nitric oxide-based heart medication for African Americans with congestive heart failure; and (3) the paradoxical outcomes for patients with hypertension and left ventricular hypertrophy, with non-African Americans showing a better response to  $\beta$ -blockers.”)

<sup>100</sup> *Id.* at 104 (emphasis on healthcare added).

<sup>101</sup> Soo-Jin Lee, *supra* note 84 at 2134.

## OBESITY LITIGATION

A string of recent lawsuits have targeted fast food companies, alleging a failure to warn their consumers of the potential harm of ingesting a steady diet of fast food products. Modeled after the successful lawsuits against tobacco manufacturers, consumer groups have brought class action cases against several major fast food manufacturers.<sup>102</sup> The groups rely on the changes subsequently implemented by the tobacco industry “as supposed proof that litigation increases public knowledge, forces companies to stop objectionable marketing practices, and drives up prices for the targeted items, which in turn reduces consumer demand for allegedly unhealthy choices.”<sup>103</sup> The first of these cases to make it in to court was a 2003 case alleging that “foods from McDonald’s were dangerous beyond the extent ordinarily understood by consumers, that McDonald’s negligently failed to warn consumers of the risks, and that the company’s marketing constituted deceptive business practices under the state’s consumer-protection laws.”<sup>104</sup> The lawsuit was eventually settled,<sup>105</sup> but not before the U.S. House of Representatives introduced a bill in 2004, known as the “Cheeseburger Bill,” with the goal of preventing future such lawsuits.<sup>106</sup> The bill did not receive approval in the Senate, but it spurred several states to act on their own. As of 2006, twenty-one states had passed laws exempting fast food chains from obesity lawsuits.<sup>107</sup> Another lawsuit filed in 2006 targeted Kentucky Fried Chicken’s use of

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<sup>102</sup> Sarah Taylor Roller, Theodore Voorhees, and Ashley Lunkenheimer, *Obesity, Food Marketing and Consumer Litigation: Threat or Opportunity?* 61 Food & Drug L.J. 419, 428 (2006).

<sup>103</sup> *Id.* at 429.

<sup>104</sup> Michelle M. Mello, David M. Studdert, and Troyen A. Brennan, *Obesity- The New Frontier of Public Health Law*, 354 N. Engl. J. Med. 2601, 2602-03 (2006).

<sup>105</sup> Ten Fat Law Suits (including 2 threatened ones) Have Been Successful -- While One is Still Pending, <http://banzhaf.net/suefat.html> (website tracking obesity litigation) (last visited May 16, 2008).

<sup>106</sup> The Center for Consumer Freedom, A Timeline of Trial Lawyers and Obesity Lawsuits, [http://www.consumerfreedom.com/article\\_detail.cfm/article/159](http://www.consumerfreedom.com/article_detail.cfm/article/159) (last visited May 16, 2008); CNN.com, ‘Cheeseburger bill’ puts bite on lawsuits, <http://www.cnn.com/2005/POLITICS/10/20/cheeseburger.bill/index.html> (last visited May 16, 2008).

<sup>107</sup> Mello, Studdert, and Brennan, *supra* note 104.

trans fats in its fried chicken.<sup>108</sup> The chain of fried chicken restaurants has since removed trans fats from most of its products.<sup>109</sup>

## TOBACCO REGULATION

Nearly every article on efforts to reduce or eliminate health disparities mentions tobacco control as an important objective. FDA's efforts to regulate tobacco product manufacturing and advertising are perhaps one of the agency's most publicized public health initiatives. In 1996, the FDA attempted to assert regulatory authority over cigarettes and smokeless tobacco as "delivery devices for nicotine, an addictive drug." The Federal Food Drug and Cosmetic Act (FDCA) defines "drugs" as "articles (other than food) intended to affect the structure or any function of the body."<sup>110</sup> The agency drafted a regulatory rule that defined tobacco products as combination products – or products that are made up of both drugs and devices.<sup>111</sup> Since the FDA has discretion to choose whether to regulate such combination products as a drug, device, or biologic product,<sup>112</sup> the agency chose to regulate tobacco products as devices because the device regulatory provisions "offer the agency greater regulatory flexibility than do the drug provisions of the act."<sup>113</sup>

In the 2000 case of *FDA v. Brown & Williamson*, the Supreme Court invalidated the FDA's assertion of regulatory authority.<sup>114</sup> In its decision, the Court found that in passing the FDCA, Congress had not intended to afford the FDA regulatory authority over tobacco

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<sup>108</sup> Roller, Voorhees, and Lunkenheimer, *supra* note 102.

<sup>109</sup> Associated Press, *KFC, Taco Bell Complete Switch to Trans-Fat-Free Oil*, MSNBC.com (April 30, 2007), <http://www.msnbc.msn.com/id/18383687/> (last accessed May 16, 2008).

<sup>110</sup> 21 U.S.C. § 321(g)(1)(C)

<sup>111</sup> C. Stephen Redhead and Vanessa Burrows, *FDA Regulation of Tobacco Products: A Policy and Legal Analysis* (CRS Report for Congress) 5 (2007).

<sup>112</sup> *Id.*

<sup>113</sup> *Id.* at 6.

<sup>114</sup> See 529 U.S. 120 (2000).

products.<sup>115</sup> The Court reasoned that since the FDCA prohibits the marketing of any product that is not “safe and effective,” the FDA would be forced to ban cigarettes and smokeless tobacco, products that have proven to be unsafe – an action that “would plainly contradict congressional intent.”<sup>116</sup> The Court’s holding “made it clear the Congress would have to enact legislation giving FDA statutory authority over tobacco products in order for the agency to assert jurisdiction.”<sup>117</sup> Congress answered by drafting language providing the FDA with such authority in the 105<sup>th</sup> and 107<sup>th</sup> Congresses, but none of the bills were ultimately successful.<sup>118</sup>

In February of 2007, “lawmakers reintroduced bipartisan, bicameral legislation . . . to give the Food and Drug Administration (FDA) broad new authority to regulate the manufacture, distribution, advertising, promotion, sale, and use of cigarettes and smokeless tobacco products.” The bill, the Family Smoking Prevention and Tobacco Control Act proposes to “create a new Chapter IX in the Federal Food, Drug, and Cosmetic Act . . . solely for the regulation of tobacco products.”<sup>119</sup> The provisions of the bill would allow the FDA to:

(1) restrict tobacco advertising and promotions, especially to children; (2) develop standards that require changes in tobacco product composition and design, such as the reduction or elimination of toxic chemicals; and (3) require manufacturers to obtain agency approval in order to make reduced-risk and reduced-exposure claims for their products.<sup>120</sup>

Somewhat surprisingly, the largest cigarette manufacturing company, Philip Morris, supports the proposed bill. The company had earlier announced its support for FDA regulation of cigarettes in a 2001 white paper.<sup>121</sup> The Philip Morris statement said:

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<sup>115</sup> Redhead and Burrows, *supra* note 111.

<sup>116</sup> *Id.*

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*; Family Smoking Prevention and Tobacco Control Act, H.R. 1108;S.625, 110<sup>th</sup> Cong. (1<sup>st</sup> Sess. 2007).

<sup>120</sup> *Id.* (numbering added).

<sup>121</sup> *Id.* at 16.

FDA should require that ingredients added by the manufacturers do not increase the inherent risks or addictiveness of smoking . . . [and] should continue to address the broad issues of disclosure (e.g., the content of warning labels, information about ingredients and smoke constituents) so that adults [sic] smokers remain informed about health risks.<sup>122</sup>

However, the white paper stressed the need for adult autonomy and argued that the FDA should be able to “discourage their consumption, but should not restrict an adult’s ability to make a decision about smoking.” Additionally, Philip Morris felt that “[t]he agency should have the authority to impose mandatory design changes to cigarettes to help reduce harm, provided the changes do not significantly diminish adult smokers’ enjoyment of the product.”<sup>123</sup>

If the legislation passes, it would allow the FDA to “require tobacco companies to disclose the ingredients in their products, remove harmful ingredients and ‘stop misleading the public about the dangers of smoking.’”<sup>124</sup> Providing the FDA with the authority to regulate tobacco products is an important step in the effort to eliminate racial and ethnic health disparities. The harmful effects of cigarette smoking, on minority communities in particular, have been well documented. “[A]lthough whites are more likely than blacks to be smokers, blacks die at higher rates of smoking-related diseases.”<sup>125</sup> Additionally, “[a]ggressive promotional marketing of tobacco products, alcohol, and unhealthy foods exploits the vulnerability of individuals and populations and targets specific population subgroups, including young people, members of ethnic minorities, and low-income populations.”<sup>126</sup> According to former Surgeon General David Satcher, “The tobacco companies get away with these harmful practices because no government agency currently has any real authority over how tobacco

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<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

<sup>124</sup> eMaxHealth.com, FDA to Regulate Tobacco Ads Targeted at Minority Communities, <http://www.emaxhealth.com/58/16471.html> (last visited May 16, 2008).

<sup>125</sup> *Id.*

<sup>126</sup> Derek Yach, *Chronic Diseases, in Social Injustice and Public Health* 253, 264 (Barry S. Levy and Victor W. Sidel eds., 2006).

products are manufactured or marketed.”<sup>127</sup> The proposed law would “authorize the FDA to regulate the advertising and promotion of tobacco products in order to protect public health [and would] give FDA the authority to modify the composition of tobacco products in order to protect public health.”<sup>128</sup> These two provisions are particularly important in addressing smoking trends in minority communities. Tobacco companies have historically targeted minority communities through focused cultural promotions.<sup>129</sup> There is also evidence that tobacco manufacturers hired professional basketball players to become spokesmen and sponsored jazz festivals to appeal to the African American community.<sup>130</sup> The preference among African American smokers for menthol cigarettes is likely a result of this targeted marketing. Minority smokers tend to favor menthol flavored cigarettes, whose cooling effect may increase their exposure to nicotine and other harmful chemicals in cigarettes by allowing smokers to inhale more deeply.<sup>131</sup> “National Cancer Institute data shows that African-American men get lung cancer at a rate 50 percent higher than white men — a gap that most scientists say cannot be fully explained by historically

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<sup>127</sup> eMaxHealth.com, *supra* note 124.

<sup>128</sup> Redhead and Burrows, *supra* note 111 at 1.

<sup>129</sup> Stephanie Saul, *A Flavoring Seen as a Means of Marketing to Blacks*, N.Y. Times, May 13, 2008, <http://www.nytimes.com/2008/05/13/business/13mentholside.html?scp=1&sq=A%20Flavoring%20Seen%20as%20a%20Means%20of%20Marketing%20to%20Blacks%20&st=cse> (last visited May 16, 2008). (“The migration of African-Americans to urban manufacturing centers after World War II, coupled with the emergence of black-oriented newspapers and magazines, created various opportunities for niche marketing. In the case of cigarettes, with research showing a slight black preference for Kools, a menthol brand, the industry saw an opening to appeal to black smokers.”).

<sup>130</sup> *Id.*

Elston Howard, who became the first black player for the New York Yankees in 1955, was hired as a Kool spokesman. By 1978 Lorillard, Newport’s maker, had borrowed the singer James Brown’s hit single, “Papa’s Got a Brand New Bag” for its marketing message, “Newport is a whole new bag of menthol smoking.” Dr. Gardiner’s paper, published in 2004 in the journal *Nicotine and Tobacco Research*, also notes that by the 1980s, Brown & Williamson, the maker of Kool, had started its Kool Jazz Festival to appeal to the same market. *Id.*

<sup>131</sup> Stephanie Saul, *Cigarette Bill Treats Menthol With Leniency*, N.Y. Times, May 13, 2008, [http://www.nytimes.com/2008/05/13/business/13menthol.html?pagewanted=1&\\_r=1&adxnnlx=1210854544-3oYW68aejldCuPURJt4PwQ](http://www.nytimes.com/2008/05/13/business/13menthol.html?pagewanted=1&_r=1&adxnnlx=1210854544-3oYW68aejldCuPURJt4PwQ).

higher rates of smoking by black men.”<sup>132</sup> There is also evidence to suggest that menthol cigarettes are more addictive.<sup>133</sup> Unfortunately, the proposed bill exempts menthol from the list of “characterizing flavors” that would be prohibited.<sup>134</sup> However, the law would authorize FDA to “develop product standards to reduce nicotine, reduce or eliminate other harmful constituents, or otherwise modify the composition and testing of tobacco products, if it determined that such regulation was appropriate to protect the public health.”<sup>135</sup>

FDA would be required to make [a product standard] determination based on a consideration of the risks and benefits to the population as a whole, which is the approach favored by public health officials. Unlike some of the previous FDA tobacco bills, there is nothing in H.R. 1180/S. 625 to prevent the agency from requiring changes in the composition of tobacco products that would render them ‘unacceptable for adult consumption.’ Placing that restriction on FDA’s ability to modify tobacco products had been a key requirement for the industry.<sup>136</sup>

Thus, it remains to be seen whether the industry will wholeheartedly support this legislation without such a restriction.

## TOXIC PLASTIC

Within the last month, increasing attention has focused on the potential risk posed by the leeching of toxic chemicals from certain plastic containers. The National Toxicology Program (NTP), housed within the U.S. National Institute of Environmental Science, released a report warning of the potential dangers of exposure to a chemical found in plastic bottles and canned

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<sup>132</sup> *Id.*

<sup>133</sup> *Id.*

“There is evidence from different studies that it’s harder to quit menthol cigarettes,” said Dr. Neal L. Benowitz, a pharmacologist and professor at the University of California, San Francisco and one of the nation’s leading tobacco researchers. He calls menthol a “public health risk.” One theory suggests that menthol in cigarettes, by providing an additional pleasurable sensory cue to smokers, reinforces addiction.

<sup>134</sup> Redhead and Burrows, *supra* note 111 at 23.

<sup>135</sup> *Id.* at 23-24.

<sup>136</sup> *Id.* at 23-24.



goods.<sup>137</sup> The chemical, Bisphenol-A (BPA) is used to make “epoxy resin and polycarbonate plastic products, including some kinds of water bottles, baby bottles, and food storage and heating containers. It is also used in the lining of metal food cans.”<sup>138</sup> According to the Centers for Disease Control and Prevention (CDC), “[m]ore than 90 percent of Americans are exposed to trace amounts of bisphenol. . . . The chemical leaches out of water bottles, the lining of cans and other items made with it.”<sup>139</sup> Exposure to the chemical is increased if the plastic is heated.

The NTP study found that rats exposed to low doses of BPA developed precancerous tumors, urinary tract problems and experienced early onset of puberty.<sup>140</sup> The NTP report concluded that “there is *some concern* for neural and behavioral effects in fetuses, infants, and children at current human exposures.”<sup>141</sup> On the five-level scale of concern used by the NTP and the Center for the Evaluation of Risks to Human Reproduction (CERHR), *some concern* is the middle level.<sup>142</sup> However, despite this moderate level of concern, numerous studies have found disturbing effects from BPA exposure, such as “changes in tissue enzymes and hormone receptors as well as interacting with other hormone-response systems.”<sup>143</sup> Alarming,ly, “numerous studies indicate a wide range of health effects from exposure to bisphenol-A at significantly lower doses (as low as 2 parts per billion in some studies) than considered ‘safe’ by

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<sup>137</sup> Associated Press, Chemical in Plastic Bottles Raises Safety Questions in Government, FOXNews.com (April 16, 2008), <http://www.foxnews.com/story/0,2933,351419,00.html>.

<sup>138</sup> Alaska Community Action on Toxics, *Bisphenol-A and Your Health* (September 2007), <http://www.mnceh.org/documents/Fact%20Sheet%20Bisphenol.pdf>.

<sup>139</sup> Associated Press, *supra* note 137. (“The doses being used [in the animal studies], Butcher notes, are not terribly different from the exposure we’re experiencing at the present time.”) *Id.* (internal quotations omitted).

<sup>140</sup> *Id.*

<sup>141</sup> National Institute of Environmental Health Sciences, *Since You Asked – Bisphenol A*, [www.niehs.nih.gov/news/media/questions/sya-bpa.cfm](http://www.niehs.nih.gov/news/media/questions/sya-bpa.cfm) (last visited May 16, 2008) (“The NTP also has *some concern* for bisphenol A exposure in these populations based on effects in the prostate gland, mammary gland, and an earlier age for puberty in females.”).

<sup>142</sup> *Id.*

<sup>143</sup> Alaska Community Action on Toxics, *supra* note 138.

the EPA.”<sup>144</sup> One study found that “women with a history of recurrent miscarriage had average blood serum levels of bisphenol-A at 2.59ng/ml, more than three times higher than women with successful pregnancies.”<sup>145</sup> Researchers have also found evidence that exposure to the chemical can increase insulin resistance and may increase the risk for type II diabetes and hypertension.<sup>146</sup>

The implications of the findings for infants and young children are particularly troubling because they “are more likely to absorb more toxins . . . because they . . . eat and drink more in proportion to their body weight than do adults.”<sup>147</sup> While BPAs are a health concern for anyone exposed, poor people may be particularly disadvantaged because they may not be able to afford to follow the guidance that recommends reducing consumption of canned goods, which are typically one of the cheapest grocery options available.<sup>148</sup> Additionally, while several retailers have pulled bottles containing BPA and manufacturers have begun to implement changes,<sup>149</sup> there currently is no alternative to the plastic liners in cans that contain BPA<sup>150</sup> Thus, absent government intervention, certain populations may not be able to decrease their exposure to this harmful chemical.

While the National Toxicology Program report has raised awareness about this harm, the program has no regulatory authority to act on these concerns.<sup>151</sup> The publicity is raising worry that the current regulatory system for toxic chemicals is dangerously outdated. Toxic chemicals

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<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> Sara Rosenbaum and Chung-Hi H. Yoder, Children, in *Social Injustice and Public Health* 88, 98 (Barry S. Levy and Victor W. Sidel eds., 2006).

<sup>148</sup> Alaska Community Action on Toxics, *supra* note 138.

<sup>149</sup> Tara Parker-Pope, *A Hard Plastic Is Raising Hard Questions*, N.Y. Times, April 22, 2008.

While there is debate about how much of a health worry BPA really is, retailers including Wal-Mart have said they are withdrawing baby products made with it. Nalgene, the maker of a popular sports bottle, and the baby-products maker Playtex have announced they will stop using it. *Id.*

<sup>150</sup> David Biello, Consumer Alert: Plastics in Baby Bottles May Pose Health Risk, *Scientific American*, April 21, 2008, <http://www.sciam.com/article.cfm?id=plastics-in-baby-bottles-may-pose-health-risk> (last visited May 16, 2008).

<sup>151</sup> National Institutes of Environmental Health Sciences, *supra* note 141.

in food products are regulated under the Toxic Substances Control Act (TSCA), which reportedly has the distinct honor of being “the only major environmental or public health statute that has never been updated” since its enactment in 1976.<sup>152</sup> The Environmental Protection Agency (EPA), which administers the TSCA, “considers exposure to 50µg/kg/day of bisphenol-A safe, [but] this standard was set in 1993 and is based on studies from the 1980s.”<sup>153</sup> While the EPA ultimately has regulatory authority over the approval of such substances for use in manufacturing plastics, the FDA is responsible for protecting against the introduction of such chemicals into the food supply. However, “[t]o date, the U.S. Food and Drug Administration has not performed a standard toxicology study or determined an Acceptable Daily Intake (ADI) for bisphenol-A.”<sup>154</sup> The regulation of chemicals that are involved in food storage is an area in which the EPA and FDA should especially collaborate effectively to ensure the health of the public.

In response to the report, a number of state governments and foreign countries have already taken action to restrict or ban the use of BPA. Canada immediately proposed a ban on the chemical in baby bottles. In announcing the ban, Tony Clement, the Canadian health minister stated, “We have concluded that it is better to be safe than sorry.”<sup>155</sup> So far, the U.S. government response has been minimal.<sup>156</sup> The FDA has formed a BPA task force “to facilitate cross-agency review of current research and new information on BPA for all FDA regulated products.” The charge of the group is to “make recommendations to the Commissioner

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<sup>152</sup> Alaska Community Action on Toxics, *supra* note 138; Environmental Working Group, Down the Drain: Sources of Hormone-Disrupting Chemicals in San Francisco Bay, [www.ewg.org/reports/downthedrain](http://www.ewg.org/reports/downthedrain) (last visited May 16, 2008).

<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

<sup>155</sup> Biello, *supra* note 150.

<sup>156</sup> *Id.* (“The House Committee on Energy and Commerce is investigating the potential dangers of BPA and how the FDA and manufacturers concluded that it was safe.”)

regarding next steps.”<sup>157</sup> In the meantime, the FDA has issued the following statement on its website:

At this time, FDA is not recommending that anyone discontinue using products that contain BPA while we continue our risk assessment process. However, concerned consumers should know that several alternatives to polycarbonate baby bottles exist, including glass baby bottles.<sup>158</sup>

## **V. OPPORTUNITIES FOR ACTION**

While the FDA has taken some actions that contribute to efforts aimed at eliminating racial and ethnic health disparities, such actions have not necessarily been framed as part of a coordinated effort to address these inequities. In addition to framing strategies around the issues outlined above, the following suggestions outline areas in which the FDA can further commit to fighting health disparities.

### **OFFICE OF MINORITY HEALTH IN FDA**

Congress passed legislation in 1994 that created the Office of Women’s Health within the FDA.<sup>159</sup> However, legislation that would create a similar focus on minority health within the FDA has stalled.<sup>160</sup> Since 1994, the increased focus on women’s health has also brought attention to racial and ethnic groups as another minority population with specific health-related

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<sup>157</sup> U.S. Food and Drug Administration, Bisphenol A (BPA), <http://www.fda.gov/oc/opacom/hottopics/bpa.html> (last visited May 16, 2008).

<sup>158</sup> *Id.*

<sup>159</sup> FDA OFFICE OF WOMEN’S HEALTH, PROTECTING AND ADVANCING WOMEN’S HEALTH: 10 YEARS AND BEYOND, available at: <http://www.fda.gov/womens/reports/report0306.pdf>.

<sup>160</sup> See Hughes, *supra* note 38; Barack Obama – U.S. Senator for Illinois, *supra* note 34. The proposed Minority Health Improvement and Health Disparity Elimination Act calls for the creation of an advisory committee on pharmacogenomics (Section 302(c)) and mandates that the FDA Commissioner participate in helping to develop an agency-wide “National Plan to Improve Minority Health and Eliminate Health Disparities.” (Section 1707(a)(2)). Minority Health Improvement and Health Disparity Elimination Act, H.R.3333/S.1576, 110<sup>th</sup> Cong. (1st Sess. 2007).

concerns. The Food and Drug Administration Modernization Act (FDAMA) of 1997 directed the development of “guidance, as appropriate, on the inclusion of women and minorities in clinical trials.”<sup>161</sup>

Accordingly, the Center for Drug Evaluation and Research (CDER) within the FDA commissioned an ad hoc working group to study and implement the 1997 directive.<sup>162</sup> The group “recommend[ed] that the Centers consider instituting a permanent tracking system to monitor effectiveness and safety data for gender and racial subgroups submitted under the new final rule,”<sup>163</sup> and delegated the task of designing such a system to the “FDA Office of Women’s Health, Gender Effects Steering Committee, CDER senior management team, and CDER’s Women’s Health Subcommittee of the Medical Policy Coordination Committee.”<sup>164</sup> It is curious, however, that the tracking of racial and ethnic minority data was undertaken by a steering committee focused on women’s issues. The inclusion of racial subgroups seemed to be an afterthought. The FDA should consider either forming an entirely separate Office of Minority Health or expanding the existing Office of Women’s Health to show a true commitment to eliminating disparities. The Working Group even seems to acknowledge its limitation:

The portion of the 1993 Gender Guideline cited above clearly articulates the expectation of FDA that all appropriate demographic subgroups should be included in product development, but the fact that this statement is found in the Gender Guideline conceivably might diminish its impact on minority recruitment.<sup>165</sup>

However, in explaining the focus on women as opposed to minorities, the committee reports that “[u]nlike women with childbearing potential, there has never been a *regulatory* barrier to the

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<sup>161</sup> FDA Women and Minorities Working Group, <http://www.fda.gov/CDER/GUIDANCE/women.pdf> (last visited May 16, 2008).

<sup>162</sup> *Id.*

<sup>163</sup> *Id.*

<sup>164</sup> *Id.*

<sup>165</sup> *Id.*

inclusion of minorities in clinical trials and there does not exist a guidance that addresses only the issue of minority enrollment in clinical trials.”<sup>166</sup> This statement demonstrates that the Working Group either does not recognize or has chosen to ignore the history of racism and exclusion in the relationship between minorities and the health care system. It is also notable that of the fourteen representatives of the FDAMA Women & Minorities Working Group listed in the report, not one appears to have a background or specialty focus in health disparities or minority health, despite the existence of the HHS Office of Minority Health at the time, which could have supplied a representative.<sup>167</sup> In a similar oversight, a representative from NIH’s Office of Research on Women’s Health was included, but there was no corresponding representative from the NIH’s Office of Research on Minority Health, which had been in existence since 1990.<sup>168</sup>

Due in part to the efforts of the OWH, the FDA in 1998 “required that anyone enrolled in clinical studies be identified by gender, age, and race and that safety and effectiveness data be evaluated to identify differences based on these same categories.”<sup>169</sup> Thus, while the existence of the OWH has benefited minority health by mandating greater collection of data on race in clinical studies, the persistence of racial disparities shows that a more focused approach is needed. Addressing the role of race in health can no longer be considered an ancillary issue.

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<sup>166</sup> *Id.*

<sup>167</sup> *Id.* The Working Group members represented the following offices or agencies: Office of Women’s Health, Center for Drug Evaluation and Research, Office of Operations, Office of Management Systems, Center for Biologics Evaluation and Research, Office of Legislative Affairs, General Counsel, National Institutes of Health Office of Research on Women’s Health, Center for Devices and Radiological Health, Office of Special Health Issues.

<sup>168</sup> National Center on Minority Health and Health Disparities, [http://ncmhd.nih.gov/about\\_ncmhd/history.asp](http://ncmhd.nih.gov/about_ncmhd/history.asp) (last visited May 16, 2008).

<sup>169</sup> FDA Women and Minorities Working Group, *supra* note 161.

## EXPANDING THE CONCEPT OF “FOOD SAFETY” TO COMBAT DIET-RELATED DISEASES

### The Obesity Epidemic

The increasing rate of obesity in the American population has grown into one of the most pressing health concerns, across all subpopulations. As depicted in books such as *Fast Food Nation* and in movies such as *Supersize Me*, Americans’ reliance on convenience food has led to an ever-expanding national average waistline.<sup>170</sup> Some attribute the phenomenon to increased food intake overall. As food production has become cheaper over time, pre-packaged foods with high sugar or fat contents (also known as energy-dense foods) have become particularly convenient.<sup>171</sup> It is “against this backdrop of Americans’ sedentary lifestyles” that public health messages have targeted individuals, encouraging healthy food choices and daily exercise. However, the data shows that “most Americans are aware of these recommendations but fail to adhere to them.”<sup>172</sup> As a result, it is becoming apparent that solely focusing on individual behavior as a public health intervention, while necessary, will not be sufficient to stop the growing epidemic.<sup>173</sup>

The increased weight is taking a toll on consumer health. Excess weight increases the risk for several serious medical conditions, including cardiovascular disease, stroke, and diabetes. As noted by Madelon Finkel, professor of clinical public health at the Weill Medical

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<sup>170</sup> See ERIC SCHLOSSER, *FAST FOOD NATION: THE DARK SIDE OF THE ALL-AMERICAN MEAL* (2001); *Super Size Me* (Documentary by Morgan Spurlock, 2004).

<sup>171</sup> Eric Finkelstein, Simone French, Jayachandran N. Variyam, and Pamela S. Haines, *Pros and Cons of Proposed Interventions to Promote Healthy Eating* 27 *Am. J. Prev. Med.* 163 (2004).

<sup>172</sup> Neil Schneiderman, Marjorie A. Speers, Julia M. Silva, Henry Tomes, and Jacquelyn H. Gentry, *INTEGRATING BEHAVIORAL AND SOCIAL SCIENCES WITH PUBLIC HEALTH* 43 (2000).

<sup>173</sup> *Id.*

College of Cornell University, this disease pathway is particularly apparent in minority communities:

The parallel obesity and diabetes epidemics reveal stark realities about the line between health and illness, a line that is influenced by genetics, race and ethnicity, and economics. The environment, too, influences the eating behavior of children and adolescents, as those who live in neighborhoods described as low income with high levels of poverty, low education, and low housing value are more likely to have poor dietary habits compared with those living in higher socioeconomic neighborhoods. On a national level, the risk of diabetes is at least twice as great in Mexican Americans, Puerto Rican Americans, and non-Hispanic blacks than in non-Hispanic whites, and the prevalence of physician-diagnosed diabetes continues to rise most steeply among Mexican Americans and African Americans.<sup>174</sup>

Indeed the prognosis for minority communities has been getting worse over time.<sup>175</sup> Increased morbidity from diseases such as diabetes and heart disease due to obesity has been a significant health burden for many minority groups.<sup>176</sup> This is particularly troubling with respect to efforts to eliminate health disparities because there are complicating factors that make reversal of the trend more difficult than simply advising people to eat a healthier diet. While personal behavior and food choices are a factor, research has shown that the over-consumption of fast food and processed food by certain populations cannot be attributed to voluntary choice entirely. Researchers have found that “even in geographically close neighborhoods, race predicts the availability of healthy foods. Communities with higher home values and that are homogenous

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<sup>174</sup> MADELON LUBIN FINKEL, TRUTH, LIES, AND PUBLIC HEALTH 157 (2007).

<sup>175</sup> Kennedy, *supra* note 14 at p. 453 (“Since the mid-1990s, the percentage of Hispanics, American Indians, and Alaska Natives living with diabetes has soared by nearly a third. . . . Rates of obesity have increased for all Americans, but African American women have been affected the most, with a 25 percent higher rate.”); *see also* Allen and Easley, *supra* note 30 at 50 (“The likelihood of dying of diabetes, in 2001, was nearly 63 percent higher for Latinos than for non-Hispanic whites.”).

<sup>176</sup> Allen and Easley, *supra* note 30 at 51 (“Significant health disparities among Pacific Islanders include diabetes and cardiovascular disease, both of which are linked to obesity.”)



have more supermarkets,”<sup>177</sup> and minority communities have been shown to have “higher concentrations of liquor stores, bars, fast food restaurants, and advertisements for tobacco and alcohol.”<sup>178</sup> Other studies have found that produce is 22% more expensive in poorer areas, and a typical market basket for four would cost the family 15% more in a less affluent area.<sup>179</sup>

Numerous studies have documented these barriers to obtaining nutritious food in poorer communities and show that the burden of poor food quality is not evenly distributed.<sup>180</sup> Since low-income neighborhoods tend to be disproportionately populated with racial and ethnic minorities, these populations “have a significant disadvantage when it comes to the availability of healthy foods.”<sup>181</sup> Some critics argue that the disproportionate rates of obesity are simply due to a preference for unhealthy foods; however, studies suggest that the disparity is not due to a lack of awareness of what foods are considered healthy. Researchers with the Continuing Survey of Food Consumption found evidence suggesting that “poor households do as well as non-poor households in knowing what they should purchase. They simply do not have the money to do it.”<sup>182</sup> Furthermore, economic analysis shows that consumers will buy the amount of food they can afford that “maximizes benefits such as taste and health and minimizes costs such as

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<sup>177</sup> JudyAnn Bigby, *The Role of Communities in Eliminating Healthcare Disparities*, in ELIMINATING HEALTHCARE DISPARITIES IN AMERICA: BEYOND THE IOM REPORT 221, 225 (Richard Allen Williams ed., 2007).

<sup>178</sup> *Id.*

<sup>179</sup> Schneiderman, Speers, Silva, et al., *supra* note 172 at 44 (2000).

<sup>180</sup> See, e.g., MADELON LUBIN FINKEL, TRUTH, LIES, AND PUBLIC HEALTH 158 (2007).

A study published in the *American Journal of Preventive Medicine* found that there are over three times as many supermarkets in wealthier neighborhoods than in lower income neighborhoods and four times as many in white neighborhoods than in black neighborhoods. Fast food restaurants and small corner grocery stores (bodegas) are also significantly more common in lower income neighborhoods, which suggests that in neighborhoods with fewer supermarkets or large chain stores there are limited options to buy healthy food because bodegas tend to stock less healthy food choices at generally higher prices. *Id.*

<sup>181</sup> Schneiderman, Speers, Silva, et al., *supra* note 172 at 44.

<sup>182</sup> J. Larry Brown, *Nutrition*, in SOCIAL INJUSTICE AND PUBLIC HEALTH 238, 246 (Barry S. Levy and Victor W. Sidel eds., 2006).

financial burden or losing health.”<sup>183</sup> Thus, cash-strapped families will tend to choose cheaper, but more filling calorie-dense foods to stretch their budgets and stave off hunger.<sup>184</sup>

### **Past Strategies**

While the previous public health initiatives advising consumers to take notice of the quantity of their consumption and to be aware of the skewed perception of portion size<sup>185</sup> should continue, it is time to more closely scrutinize the components of the processed convenience foods that Americans are ingesting in ever-increasing quantities. According to at least one report, “the single most important strategy [in reducing health disparities] would be to prevent and reverse obesity in poor and marginalized populations.”<sup>186</sup> To this end, the FDA should approach obesity with the same urgency as it would any other epidemic. Historical approaches to other public health epidemics have included “targeted regulations, taxes, and policies at either the community or individual level to limit population exposure to substances or behaviors known to promote the epidemic.”<sup>187</sup> Efforts to reduce the alarming obesity epidemic should be no different. The abundant data showing that the poor nutrition of disadvantaged populations is not merely a choice proves that the quality of fast food and convenience food is a public health

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<sup>183</sup> Finkel, *supra* note 174 at 162.

<sup>184</sup> Michael Marmot and Ruth Bell, *The Socioeconomically Disadvantaged*, in SOCIAL INJUSTICE AND PUBLIC HEALTH 25, 34-35 (Barry S. Levy and Victor W. Sidel eds., 2006). In the United States, there is an inverse association between energy density of foods (in calories per kilogram) and energy cost (per calorie); that is, cheaper foods have more calories per weight. However, high-energy density usually means fats and added sugars. Given that low income means, among other things, lower expenditure on food, this may help explain the link between lower socioeconomic status and obesity. *Id.*

<sup>185</sup> See Food Labeling: Serving Sizes of Products That Can Reasonably Be Consumed At One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes, 70 Fed. Reg. 17011 (April 4, 2005), available at <http://www.cfsan.fda.gov/~lrd/fr05404c.html>.

<sup>186</sup> Institute for Alternative Futures, *supra* note 1 at 3.

<sup>187</sup> Finkelstein, French, Variyam, et al., *supra* note 171.

concern that needs to be addressed through the regulatory authority of the FDA by implementing changes that will have a beneficial effect.<sup>188</sup>

The FDA has taken steps in recent years to increase public awareness of the nutrition content of foods; however, “[g]iven the current obesity epidemic, the question is whether additional government interventions are warranted.”<sup>189</sup> Current proposals include “nutrition guidelines for foods sold anywhere in schools; mandated nutrition labeling in restaurants and ‘food-away-from-home sources’; targeted taxes and subsidies; and a redesign of the federal Food Stamp Program.”<sup>190</sup> The labeling standards promulgated in 1990 provided consumers with detailed ingredient information on packaged foods, but exempted restaurants.<sup>191</sup> More recently, the FDA issued a final rule in 2003 requiring manufacturers to list the amount of trans fats in their products.<sup>192</sup> While these labeling provisions were necessary, they will not address the root cause of the disparity – access to and affordability of healthy food. Thus, minority populations remain disproportionately impacted and unprotected from the harmful contents of fast food because they do not always have the choice to consume in moderation. Under the Food Drug and Cosmetic Act (FDCA), the FDA has the authority to establish “reasonable standard[s] of quality” for foods.<sup>193</sup> The FDA should consider utilizing this authority to mandate better quality of all foods, particularly with regard to ingredients known to be harmful to health, such as trans fats and excess amounts of sodium.<sup>194</sup>

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<sup>188</sup> *Id.*

<sup>189</sup> *Id.*

<sup>190</sup> *Id.*

<sup>191</sup> Roller, Voorhees, and Lunkenheimer, *supra* note 102 at 423.

<sup>192</sup> Food Labeling; Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements; Final Rule and Proposed Rule, 68 Fed. Reg. 41434 (July 11, 2003) (codified at 21 C.F.R. pt. 101).

<sup>193</sup> 21 USC § 341 (2006).

<sup>194</sup> See Joanna M. Paladino, *Obesity and Public Policy*, in TRUTH, LIES, AND PUBLIC HEALTH 172 (2007).

## The Trans Fat Debate

Trans fats are a type of unsaturated fat that is created by adding hydrogen to oil, such as vegetable cooking oil. The process of partially hydrogenating cooking oils is used to increase the shelf life by eliminating the linolenic acid in the oil that would otherwise turn the oil rancid over time.<sup>195</sup> The byproduct of this process results in trans fats in foods cooked with hydrogenated oils – which is associated with an increased risk of cardiovascular disease.<sup>196</sup> Trans fats have been referred to as “absolutely the worst type of fat,” and consumers have been advised to eliminate products containing trans fats from their diets altogether.<sup>197</sup> The FDA issued a rule in 2003 requiring that all food manufacturers list the trans fat content of their products on the food label within the next three years.<sup>198</sup> While this action fell short of a ban, the “sunshine effect” of being forced to disclose trans fat content may pressure the corporations to develop trans-fat free alternative products.<sup>199</sup> Indeed, there is some evidence that this pressure is leading companies to stop using partially hydrogenated oils.<sup>200</sup> However, the FDA should not

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As confusion typifies anti-obesity policies, Americans are getting fatter. It is one thing to consider mandating nutrition labels on menus, or improving school lunch programs, or even imposing taxes on high-calorie, low-nutrition foods, but what would probably be a better tactic is to regulate the food and drink industry to ensure that the foods produced are nutritionally in line with existing guidelines and regulations. Reducing the use of saturated and trans fats in food products, for example, reducing the sodium content in prepared foods, and encouraging the consumption of fruits, vegetables, and fiber, would be a good start to help people eat a more healthy diet. *Id.*

<sup>195</sup> See Harvard School of Public Health, *The Nutrition Source: Shining the Spotlight on Trans Fats*, [http://www.hsph.harvard.edu/nutritionsource/nutrition-news/transfats/#where\\_do\\_TF\\_come\\_from](http://www.hsph.harvard.edu/nutritionsource/nutrition-news/transfats/#where_do_TF_come_from) (last visited May 21, 2008).

<sup>196</sup> Paladino, *supra* note 194 at 160.

<sup>197</sup> *Id.*

<sup>198</sup> See Mello, *supra* note 104; Food Labeling; Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements; Final Rule and Proposed Rule, 68 Fed. Reg. 41434 (July 11, 2003) (codified at 21 C.F.R. pt. 101).

<sup>199</sup> Finkelstein, French, Variyam, et al., *supra* note 171.

<sup>200</sup> Paladino, *supra* note 194 at 160.

shy away from adopting a more direct approach to mandate removal of certain harmful ingredients.

Given the numerous studies showing the increased health risks associated with consumption of trans fats, the FDA should consider banning all foods containing trans fats as “adulterated” food products. The FDCA considers food adulterated if it “bears or contains any poisonous or deleterious substance which may render it injurious to health.”<sup>201</sup> However, if the substance is not an “added substance” it is not deemed adulterated “if the quantity of such substance in such food does not ordinarily render it injurious to health.”<sup>202</sup> Food can also be considered adulterated if it contains “any added poisonous or added deleterious substance” that is considered unsafe under section 406.<sup>203</sup> Section 406 further deems unsafe “[a]ny poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice.”<sup>204</sup> Within this regulatory framework, it is not clear whether trans fats would be considered an “added substance” or not. However, there is a plausible argument that the current levels of trans fats in fast foods are injurious to the health of those who consume such foods at the average rate of most Americans. The harm that a diet high in trans fats poses to cardiovascular health is well documented, and the FDA recommends avoiding it altogether, so it is arguably “injurious to health” in any quantity. Most importantly, trans fats *can* be avoided in the manufacturing process. The FDA can and should require food manufacturers to use alternative, safer ingredients.

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<sup>201</sup> 21 U.S.C. 342(a)(1).

<sup>202</sup> *Id.*

<sup>203</sup> 21 U.S.C. 342 (a)(2)(A).

<sup>204</sup> 21 USC 346.

An alternative approach would be to argue for restrictions on the quantity of trans fats allowed in a given food product. The FDCA allows the FDA to promulgate regulations limiting the quantity of such unsafe substances “when such substance is so required or cannot be so avoided,” as long as the action is “necessary for the protection of public health.”<sup>205</sup> If the FDA relies on this provision to regulate the *amount* of trans fat in a given food product, the agency can avoid having to implement an overall ban on foods containing trans fats.

Much of the pushback from the industry argues that there are no alternative oils that would allow the foods to retain their signature taste.<sup>206</sup> McDonald’s has yet to remove trans fats from the oil used to prepare its french fries, citing the difficulty in duplicating the taste with alternative oils.<sup>207</sup> Other chain restaurants have reduced or eliminated the use of cooking oils containing trans fats, but have acknowledged that such efforts are complicated to implement while retaining the signature tastes of their foods.<sup>208</sup>

If the FDA takes steps to ban trans fats, it will not be the first time the agency has considered or actually mandated major changes to food contents in response to public health concerns. Past examples include efforts to encourage the fortification of foods, the regulation of margarine, and attempts to regulate MSG. The fortification of foods came about due to concerns that individuals were not receiving adequate nutrition from the food supply because modern food processing methods often resulted in lower nutrient content.<sup>209</sup> Some states even mandated

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<sup>205</sup> 21 USC 346.

<sup>206</sup> Janet Adamy and Steven Gray, *New York Trans-Fat Plan Could Spur Nationwide Oil Change*, Wall Street Journal (Sept. 28, 2006).

<sup>207</sup> *Id.*

<sup>208</sup> Janet Adamy and Steven Gray, *New York Trans-Fat Plan Could Spur Nationwide Oil Change*, Wall Street Journal (Sept. 28, 2006).

<sup>209</sup> PETER BARTON HUTT, RICHARD A. MERRILL, AND LEWIS A. GROSSMAN, *FOOD AND DRUG LAW: CASES AND MATERIALS* 231 (3d ed. 2007); “By the 1950s, enrichment and fortification of foods, such as fortification of salt with iodine; fortification of milk with vitamin D; and enrichment of flour and grains

fortification of foods.<sup>210</sup> Proactive measures should be considered again to avoid the harm of trans fats. Instead of regulating to encourage the *addition* of a substance, the FDA could regulate to encourage or mandate its *removal*. Such interventions are not without precedent. In 2006, the city of New York banned trans fats in all restaurants.<sup>211</sup> Additionally, other countries have taken steps to restrict the levels of trans fats in foods without entirely banning them. The country of Denmark has placed a ban on any food with a trans fat content that exceeds 2% of the total fat.<sup>212</sup> Contrary to many of the industry objections to trans fat regulation, the restrictions in Denmark “had no noticeable effect on the availability, price, or quality of food items previously containing high amounts” of trans fats.<sup>213</sup> The FDA’s historical treatment of Margarine and Monosodium Glutamate in foods are also relevant. Both were food ingredients once considered harmful enough to warrant significant restrictions.<sup>214</sup>

## Sodium

In addition to the concerns over trans fats, the FDA should also explore ways to limit the sodium content of foods. “It has been known for decades that sodium consumption can lead to salt-induced high blood pressure and is a significant contributor to heart disease and stroke.”<sup>215</sup> Now, advocacy groups are recognizing this link and are calling on the FDA to act to protect

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with thiamin, riboflavin, niacin, and iron helped bring more healthy foods into the food supply.” Paladino, *supra* note 194 at 159.

<sup>210</sup> PETER BARTON HUTT, RICHARD A. MERRILL, AND LEWIS A. GROSSMAN, *FOOD AND DRUG LAW: CASES AND MATERIALS* 231 (3d ed. 2007).

<sup>211</sup> Roller, Voorhees, and Lunkenheimer, *supra* note 102; MSNBC News Services, *New York City passes trans fat ban*, MSNBC.com, December 5, 2006, <http://www.msnbc.msn.com/id/16051436/>.

<sup>212</sup> Steen Stender, Jørn Dyerberg and Arne Astrup, *Consumer Protection Through a Legislative Ban on Industrially Produced Trans Fatty Acids in Foods in Denmark*, 50(4) *Scandinavian J. of Food and Nutrition* 155 (2006).

<sup>213</sup> *Id.*

<sup>214</sup> See generally, Hutt, Merrill, and Lewis, *supra* note 209 at 182, 1242 (Margarine regulation); Amy Lavine, *Monosodium Glutamate (MSG) and Food Labeling Regulations*, 62 *Food & Drug L.J.* 349 (2007) (MSG regulation).

<sup>215</sup> Finkel, *supra* note 174 at 161-62.

consumers, arguing that by reducing the amount of sodium in food by half, an estimated 150,000 people's lives could be saved each year.<sup>216</sup> The American Medical Association has called on the FDA to regulate salt as a food additive.<sup>217</sup> The move would require "[p]ackaged food companies . . . to adhere to limits on allowable sodium levels for various categories of foods."<sup>218</sup> The FDA has yet to act on this proposal.

### **Alternative Strategies**

FDA interventions combating diet-related diseases have primarily focused on requiring clearer labeling. However, "[p]ast research suggests that the health benefits of additional nutritional information are modest at best."<sup>219</sup> The time has come for the FDA to take a more aggressive approach to combat the obesity epidemic that is literally killing thousands of Americans. There are other options the FDA could pursue if it declines to ban trans fats or if such efforts prove to be politically unfeasible. These strategies include tougher labeling requirements, taxing "junk foods" more heavily, and mandating that healthier foods be served in schools and through other government-sponsored food programs.<sup>220</sup> Developing more creative

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<sup>216</sup> *Id.* at 161.

<sup>217</sup> *Id.*

<sup>218</sup> *Id.*

<sup>219</sup> Finkelstein, French, Variyam, et al., *supra* note 171 at 170.

<sup>220</sup>

Robert Jeffrey (1998) suggested five possible environmental interventions that could be applied to change the current trends in weight gain. These interventions include improving the quality of the food supply; enhancing accessibility of physical activity; increasing advertising for healthy food alternatives and activity; providing economic incentives for healthy eating by taxing fat and sugar; and education about the importance of diet, exercise, and collective support of a healthy lifestyle. As was the case of tobacco, for which policies were implemented to discourage smoking (such as the creation of smoke-free settings and taxing tobacco), these recommendations will need to be addressed at a policy level. Neil Schneiderman, Marjorie A. Speers, Julia M. Silva, Henry Tomes, and Jacquelyn H. Gentry, *INTEGRATING BEHAVIORAL AND SOCIAL SCIENCES WITH PUBLIC HEALTH* 45 (2000).



approaches to address public health concerns such as obesity and other diet-related illnesses is within the FDA's authority to regulate in the interest of public health.<sup>221</sup>

### **Tougher Labeling**

Currently, the FDA exempts restaurants from the labeling requirement that applies to packaged foods.<sup>222</sup> The justification for the exception is the “belief that it is too difficult, given variations in how restaurant food is prepared, to provide accurate information on caloric or nutritional content.”<sup>223</sup> The FDA responded to calls to more strictly impose the current labeling requirements by issuing proposed rules in 2005 regarding caloric content and serving size labeling.<sup>224</sup> The demise of the nightly family sit-down dinner is one reason cited for the need for more stringent regulations of restaurant and fast food:

The increase in consumption of food away from home (FAFH) has been one of the most notable changes in U.S. food consumption patterns over the last several decades. . . . Because FAFH foods tend to be of lower nutritional quality compared with foods prepared at home, many public health advocates are implicating Americans' increased reliance on FAFH as a contributing factor to the obesity epidemic.<sup>225</sup>

While some restaurant chains have taken the initiative on their own, some states have considered legislation to require the posting of nutrition information in fast food and chain restaurants.<sup>226</sup> Many argue that given the prevalence of family meals that are eaten outside of the

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<sup>221</sup> “Expanding the scope and definition of health policy would facilitate consideration of health-promoting interventions.” . . . “Many general policy-making tools, including regulation, standard setting, and taxing and spending authorities, could be viewed through a lens of health implications and be leveraged to support health improvements.” Lurie, *supra* note 28 at 101.

<sup>222</sup> Judith Foulke, FDA Talk Paper: Nutrition Information on Restaurant Menus, Restaurant labeling exemption(July 30, 1996), <http://www.cfsan.fda.gov/~lrd/tpmenus.html> (“Unlike processed foods, restaurant menu selections are not required to supply complete nutrition information.”) *Id.*

<sup>223</sup> Mello, Studdert, and Brennan, *supra* note 104 at 2607.

<sup>224</sup> *See id.* at 2606-07.

<sup>225</sup> Finkelstein, French, Variyam, et al., *supra* note 171 at 168.

<sup>226</sup> Finkel, *supra* note 174 at 167.

home and the related public health concerns, restaurants should no longer be exempt from the nutrition labeling requirement.<sup>227</sup> While opinion polls show that Americans are generally in favor of nutrition labeling requirements,<sup>228</sup> there is some evidence to suggest that even given this information, consumers will not change their energy intake habits.<sup>229</sup> Consumer education would likely also need to be a component of these labeling initiatives if they are to have any impact.<sup>230</sup>

### **Junk Food Tax**

Yet another proposal to address the obesity epidemic involves increasing the tax on “junk foods” such as “[f]ast food, carbonated beverages, and foods high in sugar and fat.”<sup>231</sup> Similar “sin taxes” have been leveled against tobacco products to encourage individuals to quit smoking. However, such proposals are ill-advised in the effort to eliminate health disparities, since they overlook the disproportionate impact such taxes would have on minorities, who would largely bear the financial burden when attempting to purchase lower-cost foods.<sup>232</sup> Furthermore, such taxes have not necessarily been shown to effectively reduce consumption,<sup>233</sup> and polls indicate that such proposals to tax certain unhealthy foods would be unpopular.<sup>234</sup>

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<sup>227</sup> See *id.* (“Public health advocates have proposed mandating nutrition labeling in restaurants and other FAFH sources similar to the “nutrition facts” panel found on most packaged foods.”) *Id.* at 168.

<sup>228</sup> See *id.* (“The recent Harvard poll shows that 62% of Americans support a law requiring restaurants to list nutrition information on their menus, suggesting that there is some public support for this intervention.”) *Id.*

<sup>229</sup> *Id.*

<sup>230</sup> *Id.*

<sup>231</sup> *Id.*

<sup>232</sup> *Id.*

<sup>233</sup> *Id.* (“there is no evidence that a tax on these products would improve health and/or positively impact obesity rates.”).

<sup>234</sup> *Id.* at 169 (“The Harvard Forum poll shows that the majority of Americans do not support taxes on ‘junk food.’”).

## Government Food Programs and School Food Initiatives

Finally, government-sponsored food programs have been identified as another food source where quality regulation could impact public health. “Citing a higher obesity prevalence rate among low-income groups, some have suggested that the FSP [Food Stamps Program] may be a contributing factor by promoting excess food consumption.”<sup>235</sup> However, the precise direction of causality should be more fully explored. It is not clear whether lower income individuals are consuming more foods or are simply consuming foods with higher energy density (i.e. higher calorie foods with more fat/sugar content). One suggested proposal is to limit Food Stamps-eligible foods to healthy options such as fruit and vegetables.<sup>236</sup>

School lunches and other foods available on school grounds have also raised concern. School lunches must adhere to minimal nutritional values, but the U.S. Department of Agriculture’s (USDA’s) standard “focuses on whether a food has at least minimal amounts of one of eight nutrients . . . [and] does not address calories, saturated or trans fat, salt, or added sugars.”<sup>237</sup> Currently, in the absence of such standards, “dietary fat in government-approved school lunches, for example, far exceeds recommended guidelines.”<sup>238</sup> Advocacy groups have also proposed regulations restricting the food available in school vending machines, citing the link between obesity and the sugar and high fructose corn syrup in sodas and candies.<sup>239</sup> Several

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<sup>235</sup> *Id.*

<sup>236</sup> *Id.*

<sup>237</sup> Finkel, *supra* note 174 at 169.

<sup>238</sup> *Id.* at 161; *see also* Mello, Studdert, and Brennan, *supra* note 104.

<sup>239</sup> *See* Finkelstein, French, Variyam, et al., *supra* note 171 (“Cross-sectional and prospective studies have linked soft drink consumption with obesity among youth.”); Finkel, *supra* note 174 at 160. (“Evidence now clearly shows that consumption of sugar-sweetened beverages, in particular the carbonated soft drinks, are a key contributor to the epidemic of overweight and obesity.”).

school districts have taken action already.<sup>240</sup> Because efforts to regulate the health and safety of children are often more politically feasible, “school-based interventions may be good candidates for public health nutrition interventions designed to curb the obesity epidemic.”<sup>241</sup>

### **Food Safety Regulation Generally**

Generally, in regard to drugs and food additives, there are a few simple ground rules on which we can probably agree. One is that large benefits certainly justify larger risks than small benefits, and that where there is no benefit, no risk is acceptable if it can be avoided. . . . It is more difficult to document that this has indeed been the pattern of decision making for compounds at the margin of decision making.<sup>242</sup>

Given the hesitation of the FDA to intervene aggressively to combat obesity through regulation, it is likely that trans fats and sodium are food additives at the margin where the balance between risks and benefits does not clearly weigh one way or another. However, in framing the discussion as one of health inequities, “we must acknowledge the difference between publicly inflicted and privately accepted risks, namely those risks which one undertakes voluntarily and those which cannot be avoided because the rest of society imposes them upon us.” It is not entirely clear into which camp the risk of a high trans fat diet falls. Whether the significantly greater consumption of fast and processed food in minority communities is considered entirely voluntary, or is deemed unavoidable due to confounding social factors, will likely determine how aggressive an approach will be taken.

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<sup>240</sup> See Finkelstein, French, Varyiam, et al., *supra* note 171; see also Finkel, *supra* note 174 at 169 (discussing school lunches) (“USDA’s standards apply only to food sold in the cafeteria, yet today vending machines in schools have proliferated.”).

<sup>241</sup> Finkelstein, French, Varyiam, et al., *supra* note 171.

<sup>242</sup> Philip Handler, *Introduction*, in HOW SAFE IS SAFE? THE DESIGN OF POLICY ON DRUGS AND FOOD ADDITIVES 4 (1974).

## VII. MEASURING PROGRESS

As outlined in the final step of the OMH Framework, any strategic plan to eliminate racial and ethnic health disparities should also outline goals and define ways to measure progress. An initiative called the DRA Project has also outlined criteria for “identifying the most important disparity reducing advances.”<sup>243</sup> The six main criteria advocate programs that:

1. Can make a very large, measurable difference in reducing health disparities
2. [Are] [c]ost-effective enough to be applied and reapplied, or be sustainable, as necessary
3. [Are] [a]ppropriate for multiple poor and marginalized populations
4. Encourage[] participation of individuals and key stakeholders
5. Can be communicated to decision-makers and the public
6. Can be realistically applied within the next 10 years.<sup>244</sup>

Additionally, quantitative models have been developed for measuring decreases in health disparity attributed to programmatic interventions;<sup>245</sup> however, “[w]hile a number of evaluations of health disparity reducing measures have been conducted, there are no conclusive answers to the question of what approaches are likely to have the most sizeable impact. There are no clear and undisputed winners.”<sup>246</sup>

## VI. FEASIBILITY AND WEATHERING THE POLITICAL CLIMATE

*“Pretending that politics and science do not coexist is foolish, and cleanly separating science from politics is probably neither feasible nor recommended.”<sup>247</sup>*

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<sup>243</sup> Institute for Alternative Futures, *supra* note 1 at 6.

<sup>244</sup> *Id.*

<sup>245</sup> *See generally, id* at 9-10.

<sup>246</sup> *Id.* at 14.

<sup>247</sup> Lubin, *supra* note 174 at 1.

While brainstorming ways in which the FDA can play a larger role in the fight against health disparities is a necessary process, policymakers must also think realistically about what policies will be feasible to implement successfully, given the political climate. As with any intervention, ideally, there should exist evidence-based research results on which to base conclusions before the program is initiated. Unfortunately, “[t]he state of knowledge is not adequate at this time to have evidence based answers.”<sup>248</sup> While legislation has mandated the collection of data on the medical causes of health care disparities, “[l]ittle is known about the mechanisms through which nonmedical determinants, particularly those related to socioeconomic status and social conditions, affect health.”<sup>249</sup> However, many of the areas that the FDA could impact have reached the level of crisis. Levels of obesity in the population, particularly among minorities, have been termed “epidemic.” Thus, the FDA should act with the same speed with which it would address any other epidemic to implement effective policies to combat this trend.

Complicating such efforts, however is the “divided public opinion about the role of government overall, as well as the role (if any) that government should play in health.”<sup>250</sup> As evidenced by the difficulty in getting legislation addressing minority health issues passed, policy priorities have not favored legislative interventions for this problem in the past. Currently the federal response to these efforts is fragmented, and “[b]oth of the influential IOM reports indicate that the public health system – from the perspective of conventional standards and technical capacity – is in disarray.”<sup>251</sup> The report highlights the limitations of local health departments, a particularly troubling dilemma since local health departments are the most direct

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<sup>248</sup> Institute for Alternative Futures, *supra* note 1 at 4.

<sup>249</sup> Lurie, *supra* note 28 at 100.

<sup>250</sup> *Id.* at 102.

<sup>251</sup> Alonzo Plough, *Promoting Social Justice Through Public Health Policies, Programs, and Services*, in *SOCIAL INJUSTICE AND PUBLIC HEALTH* 418, 421 (Barry S. Levy and Victor W. Sidel eds., 2006).

conduit of public health messages and regulations to communities. Even regulations promulgated at the federal level are typically carried out and supervised by these local agencies. However, several recent events may indicate a public readiness for change.

John Kingdon described the combination of social and political circumstances that must be present for policies to successfully be developed and implemented as a “policy window.”<sup>252</sup> The recent media attention around the possible toxicity of plastic containers may have opened a window of opportunity for action focusing on the long-term effects of food and processing on health. Additionally, “[t]he results of recent opinion polls indicate that a majority of Americans believe that the government should be involved in fighting obesity.”<sup>253</sup> The FDA must capitalize on this public sentiment to gain support for initiatives to address the factors that impact racial and ethnic minority groups disproportionately. Most importantly, the collective will for legislative action may be building.<sup>254</sup> While the strategies outlined above represent possible regulatory steps that the FDA can take on its own to direct a greater focus of its efforts on eliminating racial and ethnic health disparities, the agency should take advantage of opportunities to help shape potential legislative approaches should the policy window open.

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<sup>252</sup> See JOHN W. KINGDON, AGENDAS, ALTERNATIVES, AND PUBLIC POLICIES (2d ed. 1995).

<sup>253</sup> Mello, Studdert, and Brennan, *supra* note 104 at 2602.

<sup>254</sup> See Hughes, *supra* note 38 (“[M]ore than thirty-six organizations representing minority and disparity groups, health professional societies, schools, and safety-net institutions have signed onto a letter demanding congressional action now.”). Also, the Racial and Ethnic Health Disparities Coalition is “leading the advocacy effort for minority health legislation.” *Id.*